Exploring the experience of Clinical Research Nurses working within acute NHS trusts and determining the most effective way to structure the workforce

A mixed methods study

Jones, Helen Claire

Awarding institution:
King's College London

Exploring the experience of Clinical Research Nurses working within acute NHS trusts and determining the most effective way to structure the workforce: A mixed methods study

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Helen Jones

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Abstract

Background

The Clinical Research Nurse (CRN) workforce has developed alongside a growing National Health Service (NHS) research infrastructure. However, evidence suggests this workforce is isolated with minimal awareness in acute trusts of the work of CRNs. There is a lack of evidence concerning how best to structure CRN teams within acute trusts.

Aim

The overall aim of the study was to explore how the CRN workforce is currently organised within NHS Acute trusts, to explore the experience of CRNs working within acute NHS Trusts and determine the most effective way to structure this workforce.

Methods

A sequential mixed methods design was used. Phase 1 comprised a national online survey sent to Lead CRNs in acute NHS trusts and a statistical analysis of National Institute of Health Research study recruitment data over the period 2010-2016. The survey response rate was 77% (111/144). Survey analysis used descriptive statistics and thematic analysis. Phase 2 comprised four purposively sampled organisational case studies which included 14 semi-structured interviews and 4 focus groups. Qualitative data were thematically analysed using NVIVO 10.

Findings

Over the last fifteen years the CRN workforce has evolved in a reactive and inconsistent manner, shaped by local and external influences. The effect of reviewing CRN workforce structures was found to have a statistically significant effect on recruitment into interventional studies. Lead CRNs have an important

role in providing leadership and direction for the workforce and a link to clinical nursing colleagues. The current NHS climate means research delivery can be difficult and often overlooked as it is not perceived as a priority. The level of support and understanding from clinical nursing colleagues impacts CRN experience.

Recommendations

- Organisations should ensure the CRN workforce is well led with the establishment of a Lead CRN post.

- A CRN workforce model is proposed to provide a suggested framework.

- Work should be undertaken to address the lack of understanding of research and the CRN role.

- R&D Departments should consider the timing of a full review of their CRN workforce.

- Work is needed to understand the role of the emerging non nursing workforce within research.

Conclusion

Development of well-structured CRN teams supported by a local leader with formal links into internal stakeholders is key. Improving integration of the CRN workforce into existing organisational structures and processes will raise the profile of research and may facilitate a longer term shift in attitudes.

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I dedicate my thesis to my amazing Dad – an eternal academic and inspiration to me who, had he been here to see me submit, I know would have been immensely proud.

Abbreviations

AUKUH	Association of United Kingdom University Hospitals
BRC	Biomedical Research Centre
BRU	Biomedical Research Unit
CNS	Clinical Nurse Specialist
CRF	Clinical Research Facility
GCP	Good Clinical Practice
HON	Head of Nursing
NHS	National Health Service
NIHR	National Institute of Health Research
PI	Principal Investigator
R&D	Research and Development
SOPs	Standard Operating Procedures

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Chapter 1: Background

1.1. Introduction

The Clinical Research Nurse (CRN) workforce is now present within most NHS acute trusts although over looked in comparison to the more conventional clinical nursing role. Over time this relatively unstudied - but growing - nursing workforce has taken root within the NHS but it is one which lacks visibility and wider awareness of its functions. This study seeks to enable a better understanding of this national workforce and understand the contemporary experiences of CRNs working within it.

The focus of this thesis is to explore the experience of Clinical Research Nurses (CRNs) working within acute National Health Service (NHS) Trusts and determine the most effective way to structure the CRN workforce. In this context this background chapter will examine the growth of the CRN role and workforce since the 1980's and the influences that have shaped this. The origins of clinical research and its importance to healthcare, as well as the external influence of the pharmaceutical industry, are discussed in relation to the CRN role and its development within the NHS. Key policies and legislation are highlighted including the more recent role played by the Department of Health.

1.2. The History of the Role of the Clinical Research Nurse

The role of the Clinical Research Nurse (CRN) has developed over the last 30 years. CRNs are now an established part of the nursing workforce across NHS organisations. This has taken place due to the many developments within NHS research infrastructure over this period including a change in the management and organisation of funding streams available to support research, as well as increasing attention to research governance requirements in order to ensure patient safety

The ongoing development of effective pharmaceutical treatments to improve patient care - supported by the pharmaceutical industry - has in part been the catalyst for the development of the CRN role. Statins are an example of a novel

treatment; launched in the UK in the 1990s this new class of drugs are now used worldwide and have led to a 50% decrease in deaths from heart attacks and strokes (Fox et al 2007). Today an estimated 30 million people are prescribed statins and millions of lives have been extended (Endo 2010). What started with the identification, by a Japanese scientist in 1976, of an enzyme involved in the metabolism of cholesterol, led to a successful drug development programme comprising 14 clinical trials and 91,000 patients (Stossel 2008). Conduct of pharmaceutical studies such as these was supported by CRNs. This led to an eventual market leader in the management of one of the most prevalent diseases of the 20th century, so demonstrating the importance of clinical research and the impact that it can have on disease and health.

1.3. Origins of clinical research and the mistakes of the past

The early evolution of a robust structure and governance support for clinical research began in the 1970s and 1980s following examples of previous unethical practices. The Nuremberg Code was created in 1947 following the Nuremberg Trials which unveiled details of the atrocities and unethical experiments carried out on Jewish prisoners during the Second World War. Later, the Tuskegee Syphilis study enrolled 400 Afro-American men diagnosed with asymptomatic syphilis and aimed to see the effect of syphilis on this group. Even when penicillin became the standard cure in 1947 these men remained untreated. This lack of treatment and unethical research practice led to many early deaths as well as transmission of the disease to partners and children (Gorbie-Smith, 1999)

History has demonstrated the negative impact of insufficient research and knowledge around a newly licensed drug and how - when used without sufficient ethical oversight - individuals could be at risk of abuse and exploitation. The Thalidomide disaster of the late 1950s and early 1960s led to the birth of approximately 10,000 babies worldwide with phocomelia (shortened, absent, or flipper-like limbs). Despite limited and poorly conducted research,

women around the world had been recommended Thalidomide as a treatment for morning sickness. This is a catastrophic example of the human impact of a lack of sufficient research and oversight.

As a result the pharmaceutical regulation industry emerged in the late 1960s. Within the United States the Food and Drug Administration (FDA) introduced amendments that required manufacturing companies to prove that a drug was not only effective but also safe. Approvals had to be based on sound science and companies had to introduce additional post marketing surveillance to monitor safety reports. Across Europe countries had already started to work together to enhance economic development. The European Economic Community (EEC) had begun in 1957 with the Treaty of Rome and the 1960s and 1970s saw the publication of a series of EU directives which focused on defining standards and practices for the development of new pharmaceutical drugs. The World Medical Association published the Declaration of Helsinki in 1964. Still seen today as a key document it defined the ethical principles for medical research involving human subjects. These guidelines form the foundation of the research governance structure that was to develop towards the end of the century (Shah and Griffin 2003).

1.4. Development of the Clinical Research Nurse role

A CRN is described as being “employed principally to undertake research within the clinical environment” (UK Clinical Research Collaboration – UKCRC 2007). The main remit of their role within the NHS is to manage the set up and running of research studies and to oversee the care of patients treated within a research study. This includes ensuring all approvals are in place prior to commencement of a study, informing patients of the study prior to obtaining written consent and managing trial related appointments and investigations during the study. The CRN becomes the patient’s advocates and often a source of support for them throughout their treatment pathway. The CRN will also support the patient during any treatment side effects or incidences that occur during the study. Known as adverse event reporting, this is part of the large amount of data collection for which CRNs are responsible (Coulson and Phelan 2000).

The CRN role has not always been part of the nursing workforce. Its early development was initiated by the pharmaceutical industry and their need for some dedicated support within drug development programmes. By the early 1980s nurses could be found working in Phase 1 units and caring for healthy volunteers participating in the studies. Phase 1 studies are the first in a series of stages within the development of a new drug. Within phase 1 the drug is tested on a small number of volunteers in order to determine the maximum tolerated dose. A further explanation of the phases of drug development is provided in table 1.

Table 1.4-1 Phases of Clinical Trials

Phase of Study	Description
I	Initial safety trials on a new medicine. Involves small numbers of healthy volunteers and aims to assess safety and not efficacy.
II	Small scale studies on relevant patient population. Objectives may focus on dose-response, type of patient, frequency of dosing, or other safety and efficacy characteristics.
III	Involve larger numbers of patients with the relevant disease. Compares the new drug against an existing treatment within the same class or a placebo to see if it's better in practice and identify any relevant side effects. Following this phase all information is submitted to the regulatory Authorities for license approval.
IV	Post marketing studies or trials conducted to provide additional details about the medicine's efficacy or safety profile.

1.5. Set up of the CRN role within the NHS

The literature available on the development of a specialist nursing role within the hospital setting specific to research and clinical trials is - at best - anecdotal; explanations of how the role evolved are most commonly found in discussions with those directly involved at the time. Initially, early studies involving hospital patients were supported and run by clinician's with direction from pharmaceutical companies; the companies provided some suggested practices in the form of guidelines as to how research using human volunteers should be conducted. Nurses were not directly involved in research developing new drugs; rather the pharmaceutical companies would approach clinicians' directly to carry out studies on new drugs under development prior to submission to the licensing authority. However, during the 1970s and 1980s nurses began to be

employed as research nurses. This was an informal process as the role was not developed within the profession and progression to it was generally related to an opportunistic discussion by a ward based nurse with a research minded clinician who wanted support for their study within a hospital setting.

Within the UK nurses were beginning to specialise in clinical areas, informed by developments within the United States where the phrase “Nurse Clinician” had been coined in the 1940s to describe a nurse with advanced education and clinical competence who remained actively engaged in clinical practice (Reiter 1966). This new role – termed a clinical nurse specialist (CNS) - was described as “a graduate professional nurse who is an expert practitioner because she has a broader knowledge, deeper insight and appreciations, and greater skills than those that can be acquired in a basic nursing course of generally accepted standards” (Mayo 1944: 580). This CNS role began to be adopted in the UK in the 1980s, typically within specialist areas such as oncology. Although not identified as such, a small amount of nurses began to shift the focus of their nursing career towards the specialism of research and by the mid to late 1980s the nursing press began to identify substantive roles within a hospital setting. So the CRN role was evolving at the same time as the more general CNS role. Within the same decade Clinical Research Units were beginning to develop to support the pharmaceutical industry in the early drug development process.

The Drug Development Unit at Guys Hospital in London was opened in 1983 and two research nurses were appointed. This role initially involved treating volunteers in Phase 1 studies covering activities such as taking blood pressure measurements and entering data. At this point it did not include taking blood samples as this was still very much seen as a clinician’s responsibility. However, within a few years the role had begun to expand in order to adequately support the needs of the studies. The nurses began to take on tasks such as the taking and processing of blood samples. This involved being trained on new pieces of equipment and so the responsibilities of the role began to develop. Within the research field the role was developing faster than the profession. There were few nurse specialists posts developed within other

areas and it remained a rare requirement for a nurse to be trained in venepuncture.

1.6. Influence of the pharmaceutical sector on CRN role development

Worldwide drug development was also seeing progress and changes that would have some impact on the developing role of nurses in clinical trials research. Simbec Research, now one of Europe's leading contract research organisations specialising in early clinical research services for the international pharmaceutical industry, was founded in 1976 in the back garden of one of its founders. Within three years it was awarded the title Small Company of the Year by the BBC for its pioneering work post the thalidomide tragedy. Quintiles, now the world's largest provider of biopharmaceutical development, was founded in America in 1982 and opened its first UK site in 1987 (Quintiles 2013). It sought to support pharmaceutical phase 1 drug development and quickly became recognised for its role in this process. These new research companies began to recruit nurses to support participants within the studies, further acknowledging their important role in the research arena. UK based pharmaceutical companies such as Roche and Glaxo also had on site phase 1 units staffed by nurses to care for participants enrolled in their research studies. This helped to further recognise the emerging role of the research nurse as this group began to develop skills in phase 1 research.

The development of guidelines to ensure international consistency within drug development began to create an ongoing requirement to ensure and confirm adherence. Within the drug licence application system pharmaceutical companies were keen to demonstrate that they had adhered to this now internationally recognised gold standard. The ongoing development of a CRN role provided a dedicated individual to ensure this and also a link between the clinician and pharmaceutical company.

1.7. Added impetus to the development of the CRN role

The late 1990s saw significant time points in the development of the research arena, impacting on the emerging role of the CRN and the need for a dedicated workforce to support this process. Two significant reports were commissioned in the 1990s following events surrounding patient deaths at two UK hospitals. The Bristol Royal Infirmary inquiry was set up in 1998 to investigate the deaths of 29 babies undergoing heart surgery in the late 1980s and early 1990s. This led to the revelation of events at the Alder Hey Children's Hospital in Liverpool where details began to emerge of children's organs being retained after their death without parental consent or knowledge. As the details of organ retention at Alder Hey began to come to light the public learned that such practices went back decades. An investigation was opened in 1999 and when the report was published two years later it revealed that that during his time at the hospital the Dutch pathologist Dick van Velzen had systematically ordered the unethical and illegal stripping of every organ from every child who had had a post-mortem (House of Commons 2001).

1.8. Growth of Research Governance

As a result of the Alder Hey and Bristol enquiries the laws governing the taking and storage of blood and tissue for research were reviewed. In 2006 the Human Tissue Act was published and became incorporated into British law. The law specifically focuses on consent of the individual and established an updated legislative framework for regulating the removal, storage, and use of human organs and tissues (Price 2005). It also established the Human Tissue Authority to oversee implementation and adherence of the legislation. A growing research governance structure was developing that provided further rationale for a dedicated workforce to ensure implementation and adherence. However, no national structure or model was in place; roles were generally developed reactively across organisations with no oversight of the workforce.

An important addition to the growth in research governance was the development of the principles of Good Clinical Practice (GCP). Now recognised

and adhered to worldwide it forms the beginning of an emerging governance structure that necessitated a dedicated workforce to support adherence, sound science, production of robust clinical research data and ongoing patient safety. Throughout the 1980s many countries began to independently develop their own guidelines related to the ethical conduct of research based on the Declaration of Helsinki. The World Health organisation brought these together in 1993 and in 1995 published the first GCP document (Otte et al 2005). In order to ensure greater international consistency within drug development the International Conference on Harmonisation (ICH) brought together the EU, Japan and the United States; the first ICH GCP guidance document was published in 1996. This set the standards in clinical research to ensure the protection of the rights and safety of trial participants and ensure the quality of the data.

However, within the UK, the GCP document was not linked to those hospital-based academic studies which did not involve drugs. Throughout the 1990s the Department of Health (DOH) had been undertaking a thorough examination of research and development within the National Health Service (NHS). This led to the publication of the Research Governance Framework (RGF) in 2001 which laid out the principles of how hospital based research should be undertaken and the responsibilities of the individuals and organisations that were carrying it out. Since 2004 it has been mandatory for NHS trusts who host research to have systems in place to ensure that the standards and principles set out in the RGF are met.

1.9. Department of Health influence on the growth of the CRN workforce and the establishing of a structure

DOH policy and strategy has supported a growth in research infrastructure. In 2000 it published the NHS Cancer Plan which identified a need for a greater focus on research to enhance patient care and treatment options. This led to the creation of the National Cancer Research Network (NCRN) and a system of 32 cancer research networks which would help support the greater involvement

of patients within research. Funding was provided to support the appointing of CRNs to work on these cancer research studies.

Within a few years the success of the NCRN was evident and by 2006, 14% of all oncology patients were being treated as part of a clinical trial, over three times that of baseline activity. In addition, nearly three hundred NCRN research nurses had been appointed and were working across the networks on a portfolio of 431 studies (NCRN 2006). The development of the NCRN had seen the first dedicated funding from the DOH being directly allocated towards establishing nursing roles to support research studies. It also provided a mechanism for researchers to widen the number of organisations who would be able to support their study.

This in part led to the DOH publishing a further document in 2006; "Best Research for Best Health"- a new five year Research and Development (R&D) strategy. Its aim was to improve the health and wealth of the nation through research and one of its goals was to "Attract, develop and retain the best research professionals to conduct people based research" (DOH 2006:2). This document recommended the establishment of the National Institute of Health Research (NIHR) which aimed to: *"create a health research system in which the NHS supports outstanding individuals, working in world-class facilities, conducting leading-edge research, focused on the needs of patients and the public". (DOH 2006:5).* This publication proved to be another significant time point in the development and growth of the CRN workforce.

The development of the NIHR infrastructure over the next 2-3 years saw the implementation of a system that was to directly impact the CRN workforce. A system of topic specific research networks, each focusing on a clinical area, was developed as well as a generic research network, known as the Comprehensive Local Research Network (CLRN) (appendix 1). This became the route by which acute hospitals received the majority of their annual allocation of research funding from the NIHR. Funding was also allocated towards establishing dedicated research units within hospitals known as Clinical Research Facilities (CRFs) as well as centres of excellence known as

Biomedical Research Centres (BRCs) or Biomedical Research Units (BRUs). With all of these units came additional funding which supported the further development of a range of research focused posts including research nurses.

Once fully established the NIHR comprised 102 research networks within a system of 8 network topic specific structures (appendix 1). Although successful in its work to continue the development of research within the NHS, by 2011 this system was thought to require improvement as there was recognition that variation in practice was putting the system at risk (Corbett-Nolan 2011). In 2011 the Good Governance Institute was asked to review the existing governance arrangements for clinical research networks. Their main recommendation was that the current system should be changed to create a rationalised, geographical pattern of networks (Corbett-Nolan 2011). From April 2014 the NIHR changed to a system of 15 geographical research networks as illustrated in Figure 1.9-1. The Clinical Research Network is made up of 15 Local Clinical Research Networks that cover England (see Figure 1.9-1). Each individual network comprises 30 clinical specialties within 6 divisions (appendix 2).

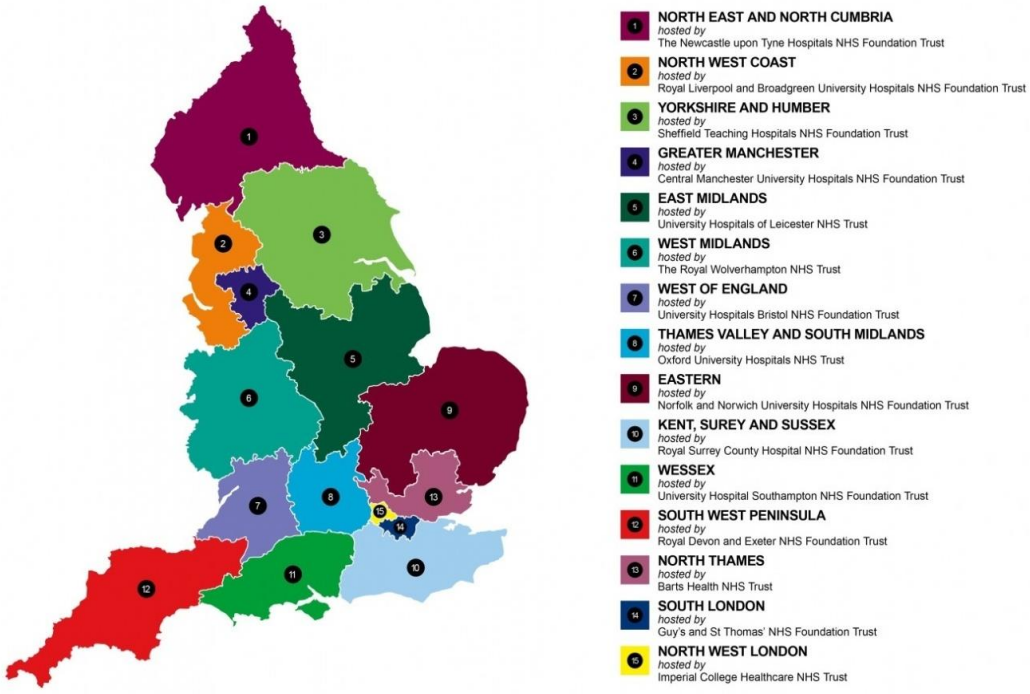


Figure 1.9-1 NIHR structure (April 2014 onwards)

1.10. The National Institute of Health Research (NIHR)

The establishment of the NIHR has had an enormous impact on research within the NHS. In 2014/2015 just under 620,000 people took part in studies hosted by the NIHR Clinical Research Network (NIHR 2016) and now all NHS Trusts are now involved in research (NIHR 2014a). It is recognised as the research delivery arm of the NHS and functions to achieve its high level objectives which include to “increase the number of participants recruited into NIHR Portfolio studies” and to “increase the proportion of studies in the NIHR portfolio” (NIHR 2015).

Understanding the mechanisms within the NIHR is key to further understanding the important role it now holds within NHS research. “Research delivery” is of relevance to all those funded by the NIHR and an understanding of its mechanisms highlights the important role held by the CRN workforce within this. Research delivery has been defined as “all the elements, systems and processes and governance that need to be in place to ensure research is effectively delivered within the NHS” (personal communication with C Morgan, Research Delivery Director, October 2016). Research delivery incorporates the running of patient centred research studies for which the CRN role is key.

An NIHR study is known as a “portfolio study” which means it has met the specific eligibility criteria defined by the NIHR and is now listed (known as adopted) on their database of studies (NIHR 2017). Portfolio studies are divided into two categories -interventional or observational. An observational study has been defined as “observing natural relationships between factors and outcomes” whereas interventional studies, also called experimental study designs, are those “where the researcher intervenes at some point throughout the study” (Thiese 2014: 199). Examples include studies developing new drug treatments or new surgical techniques. Adoption onto the portfolio is a favoured status as once achieved; researchers are able to access local research support to help run the study including the support of CRNs and other healthcare professionals and research staff.

The NIHR operates a system of “activity based funding”. Within this a large amount of the funding is allocated to organisations based on the numbers of patients who are recruited onto portfolio studies. Therefore, the greater amount of patients recruited leads to higher levels of NIHR funding to support further recruitment the following year. Hence there is a significant focus by organisations on recruitment to ensure the continuation of the funding.

1.11. Background to Research Project

A developing research infrastructure and the growth of the CRN role across the NHS supported the overall growth and establishing of a national CRN workforce. Within the first few years of the NIHR being established it was recognised that there was an ongoing increase in the number of CRN posts being developed. However, there was a lack of evidence to describe the national picture and a lack of understanding as to how the structure of the national CRN workforce had developed. Only estimates could be given as to the size of the overall workforce. Pidd et al (2013) forecast a workforce of 10,000 by 2013 but this figure lacked empirical evidence.

The development of the UK research infrastructure led to the recognition of the need for a centralised research system to co-ordinate the employment, management and development of CRNs (Ledger et al 2008). This developed infrastructure has demonstrated that the UK government has acknowledged the benefits to be derived from a well organised high quality system of research networks (Chester 2007). Ledger et al (2008) reported on the first organisation to review their CRN workforce and introduce a model for recruitment, employment, line management, training and development. Since this initial report other organisations had followed but the number and location of these was unknown. It was known, however, that there were sporadic unpublished organisational reviews of the CRN workforce but no accurate data on their numbers or review outcomes. There was also minimal data on the experience of CRNs within acute NHS trusts although many had published anecdotal reports of their own experiences.

Therefore this was planned as the first national study which aimed to provide a clearer understanding of the number of CRNS working across the UK and identify all UK acute NHS Hospital Trusts which have reviewed their CRN structure. Use of the word “review” was intended to mean a formal assessment of the roles and structure of the CRN workforce. The study aimed to explore how the CRN workforce is currently organised within NHS Acute trusts, to explore the experience of CRNs working within acute hospital trusts and to determine the most effective way to structure the CRN workforce.

The overall objectives of the study were:

- To identify acute hospital trusts which have reviewed the structure of their CRN workforce.
- To identify which acute hospital trusts have subsequently introduced a new structure.
- To explore how the CRN workforce is currently organised within NHS Acute trusts using a quality framework.
- To explore and compare the experience of Clinical Research Nurses within different organisations using a quality framework.
- To explore the experience and perception of senior research staff (R&D Directors, Lead CRN and Principal Investigators) concerning the research nurse workforce within their organisation.

1.12. The Researcher

This work was planned and carried out by an experienced research nurse with over 20 years’ experience of the role and clinical research. Having spent most of my career working as a research nurse I have seen the development of the research nurse role and the impact of the NIHR and the establishment of a national infrastructure. When I commenced my first research nurse post in 1994 there was minimal awareness of the role and research nurses were often isolated from their nursing colleagues with post holders generally being appointed by Clinicians and based within medical teams. With a growth in

research governance including Good Clinical Practice and the Research Governance Framework and the set-up of the National Cancer Research Network (NCRN) and the NIHR, I experienced not only an increase in the awareness and understanding of the role but a development of a new workforce within nursing. My early research nurse roles were based within small research teams with one or two research nurse colleagues. However, by 2007 I was working as a Lead Research Nurse within a large oncology research team. Therefore I had experienced first-hand the development of the workforce and the establishing of dedicated research nurse teams.

My current role as a Lead Research Nurse within a large acute teaching trust has enabled me to link in with similar post holders across the country. Through this national network we have been able to share best practice. Therefore at the commencement of this study I had access to a group of peer colleagues, many of whom were equally aware of the development in research and the CRN role. This provided an accessible starting place for my initial data collection to support the overall study objectives.

1.13. Summary

This background chapter has provided an overview of key influences in the development of the CRN role over the last 30 years. Within this it has sought to describe the parallel development of the research structure within the NHS, the role of the Department of Health in supporting this and the increasing governance around research to ensure that patient safety remains of paramount importance. It has set the scene for the rationale for this study and demonstrated why the researcher is best placed to carry out this work. The NIHR is now thought to fund a large amount of the CRN workforce which in turn provides support for portfolio studies. The following chapter will review the current evidence in relation to the structure of the CRN workforce and experience of CRNs within it. This will provide further evidence and justification for this study.

Chapter 2: Literature Review

2.1. Background

Clinical Research Nurses (CRN) are crucial members of the research team who acquire highly developed skills in multiple areas relating to the research process (Hill and MacArthur 2006). They have been described as a vital link between patients, principal investigators, the study sponsors and administrative staff (McKinney and Vermeulen 2000) and their positive impact on patient recruitment has long been demonstrated (Isaacman et al 1996). They are seen as having a key role in the conduct and support of research projects (Coulson and Grange 2012); their patient focused role gives them unique insights into the practical issues around research that are necessary to make it applicable to the development of ongoing evidence based care and treatment (United Kingdom Clinical Research Collaboration – 2007, Finch Report).

However, the role is often confused with that of a nurse researcher and the terms are often used inter changeably with a lack of awareness of the differences. Authors have tried to overcome this by describing the differences between these two roles (Deave 2005, Jones 2015), not least to help nurses to decide their chosen research career pathway. The CRN role involves working on projects related to treatments and patient care where as nurse researchers work on projects which are based on the acquisition of new knowledge related to the progression of nursing. There is however, recognition that CRNs are ideally placed to become nurse researchers and move between the two roles.

CRNs are now part of the nursing workforce in most if not all NHS acute hospital trusts and present in many clinical specialities. Their role has been described in clinical areas such as oncology (Bird and Kirshbaum 2006), diabetes, (Chester et al 2007), primary care (Walsh 2010) and paediatrics (Coulson and Phelan 2000). The increasing size of the national CRN workforce has supported a rise in the recognition and importance assigned to it from numerous high profile organisations. These include the Royal College of Nursing (RCN) and the National Institute of Health Research (NIHR). The RCN views CRNs as one of the “fastest growing specialism’s in healthcare delivery” and now has dedicated pages within their website to provide information and

direction for those interested in pursuing the role as a career (RCN, 2017). The NIHR, who have been instrumental in the development of the national CRN workforce through the setup of the National Clinical Research Network structure, view CRNs as vital to delivering their research and recognise their important role in providing high quality patient care and supporting the development of multi-disciplinary teams that deliver research (NIHR 2017).

The development of the CRN role and growth of the workforce size has enabled post holders to become established within research teams of CRNs. More recently other members of the multi-disciplinary team (MDT) have also developed roles dedicated to support research, such as Research Pharmacists. However, there remains little empirical evidence as to how organisations, especially those with a large number of CRNs, have structured their workforce in order to ensure effective leadership and relevant and ongoing professional development.

2.1.1. Review of the evidence

Despite the steady growth in the CRN role since the beginning of this century, there remains little empirical published work focusing on the CRN role within the UK. However, there is a growing amount of anecdotal literature that describes the wide range of responsibilities within the role with many focusing on the array of clinical areas within which post holders are based. These articles often also highlight the difficulties and challenges faced by CRNs working within a busy clinical healthcare environment.

In order to identify relevant empirical work and inform the study a literature review was undertaken to explore the following specific questions:

1) What is known about the experience of CRNs within their role?
2) What current workforce structures are in place?
3) What is known about the experience of other research staff in relation to the CRN workforce?

2.2. Methods for the Literature Review

Within the UK, the CRN role has gradually developed since the 1980's. There are sporadic articles from this time period on some aspects of the role. Due to uncertainty of when the first reviews were completed and to ensure that no potential articles were omitted, no specific time period was used when carrying out the individual database searches. The relevant inclusion and exclusion criteria are presented in Table 2.2-1. Articles from outside of the UK were excluded due to differences in healthcare systems and research infrastructure.

Table 2.2-1 Inclusion and Exclusion Criteria for literature search

Inclusion criteria
• **Primary research articles.** • **Studies published from the year the database started.** • **Articles relating to UK CRN role and UK CRN workforce.** • **Published in English language peer reviewed journals.**
Exclusion criteria
• **Articles published on roles based in countries outside of the UK as lessons not relevant to NHS based roles due to different healthcare structures.**

2.2.1. Search methods

Electronic search

Four major healthcare related bibliographic databases were searched from their year of being established to week 52 of 2016. These databases included: Medline (1946), EMBASE in Ovid SP (1974), Cumulative Index to Nursing and Allied Health (CINAHL) (1961) and the British Nursing Index (BNI) (1985). Key terms were used to explore around the research questions. Key search terms as listed in the search strategy were entered into the database to identify relevant papers (Appendix 3). This identified a large amount of papers as illustrated in the PRISMA flow diagram (Moher et al 2009) (Figure 2.2-1). Search terms were combined in order to exclude those not completely relevant to CRNs.

Search of other sources

There were two additional sources of papers – unpublished workforce studies and reference lists.

Three unpublished CRN workforce reviews (see table 2.3.2) were obtained from a leading academic who was aware of some local CRN workforce reviews. Although unpublished, they were deemed to be suitable as they matched the remaining search criteria and offered empirical data in an area which is largely unstudied.

In addition, the reference lists of all retrieved articles were also checked for any possible relevant studies.

Selection of relevant studies and extraction of data

The searches identified a total of sixty six studies which matched the search criteria. The article title and abstract were then reviewed in depth and relevant papers were selected using a data eligibility form (appendix 4) Selected studies were reviewed with my academic supervisors (GR & JP) to confirm eligibility and provide an important validity check. This resulted in five papers. These were then reviewed using a data extraction form (appendix 5). Review of papers included identification of study aims, methodology used and key findings.

2.2.2. Methodological quality

The majority of studies identified within this review were stated as being mixed methods. However, as they all had a strong qualitative element the critical appraisal tool for qualitative studies from CASP (Critical Appraisal Skills Programme) (CASP, 2014) was used to further assess the quality of the studies (appendix 6).

Excluded studies: anecdotal accounts of CRN role

In addition to the empirical papers, the search identified a total of 35 anecdotal accounts of the CRN role across the UK (see appendix 7). These include personal accounts of a CRN role (Oyebode 2012, Hemingway and Storey 2013), articles describing responsibilities within the role (Gibbs and Lowton 2012, Pick and Drew 2011) and other which highlight particular issues such as isolation, lack of understanding and poor line management (Gordon 2008). None of these had applied a systematic methodology and so present a subjective account of experience.

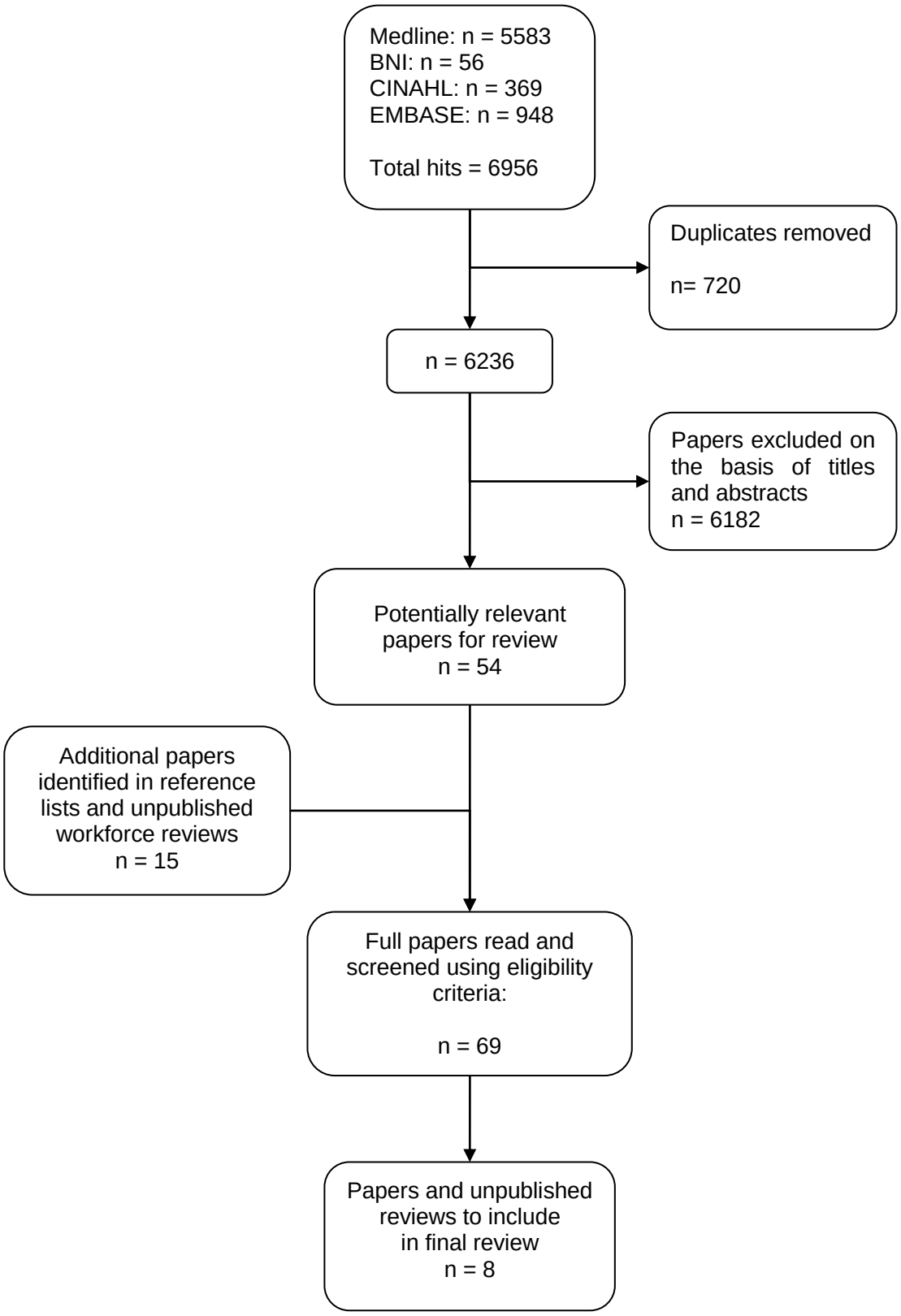


Figure 2.2-1 Summary of data search and retrieval process for the literature review using Prisma

(Adapted from Moher et al 2009)

2.3. Overview of included studies

A summary of the five studies and three workforce reviews included in this review is presented in the tables below. All of the reviewed articles and workforce reviews were published between 2006 and 2014. The overview of these five studies will be followed by the three workforce reviews and consider how each helps to address the study questions.

Table 2.3-1 Summary of peer reviewed studies.

	Study	Type of study	Data collection method	Aim
1	Hill, G & Mac Arthur, J (2006)	Mixed Methods	Postal questionnaire Focus Group interviews	To develop a profile of CRNs working across the trust
2	Spilsbury, K et al (2007)	Qualitative	Focus Group	To explore experiences of being a CRN.
3	Ledger, T et al (2008)	Mixed Methods	Questionnaire survey Overview covering pilot of new structure	To explore a method to develop the CRN workforce in a consistent manner and introduce a working framework to guide this.
4	Coulson, C & Grange, A (2012)	Mixed Methods	Questionnaire survey Interviews Focus groups	To identify CRNs within organisation, examine their role & describe their experiences.
5	MacArthur, J et al (2014)	Mixed Methods	Online survey comprising open and closed questions and free comments	Examine development of the CRN role

Table 2.3-2 Summary table of unpublished workforce reviews

	Author	Aim of review	Method used within review
1	Simpson, K (2006)	Identify and describe nursing roles involved in research across trust & university. Provide recommendations for the future.	Email questionnaire
2	Carrick – Sen (2007)	To identify all those working in a CRN role. To identify local concerns & current ways of working. To recommend new ways of working.	Mixed Methods approach to include: Postal questionnaires. One to one interviews. Group consultation.
3	Edwards, C (2008)	Identify nurses working in research across trust and university. To identify range of roles, current working practices & local issues. Develop a support strategy to incorporate education and training.	Email questionnaire

Four of the empirical articles looked at the experience of the CRN with three of them exploring as part of a local workforce review (Hill and MacArthur 2006, Spilsbury et al 2008, MacArthur et al 2012 and Coulson and Grange 2012).

Hill and MacArthur (2006) reported on two workforce reviews carried out in neighbouring organisations a year apart. Their key finding was that the CRN workforce exhibited a plethora of diverse experiences including line management structure, educational support and employment and working arrangements. Their subsequent study ten years later showed demonstrable progress in the development and recognition of the CRN role across Scotland (MacArthur et al 2014). Following their review, Coulson and Grange (2012) reported that CRNs carried out a myriad of responsibilities. Spilsbury et al (2008) carried out a focus group of nine CRNs working across the same randomised controlled trial (RCT) to explore their individual experiences and highlighted the challenges of the CRN role.

The unpublished workforce reviews (Carrick-Sen, 2007, Simpson 2006 and Edwards 2008) primarily focus on aiming to identify the local CRN workforce, recommend new ways of working and identify how best to support their professional development and training needs. Key themes identified were similar to the empirical studies. However, additional themes were also identified including leadership and research activity.

2.4. Review applied to research questions

2.4.1. Review Question 1: What is the experience of CRNs within their role?

There were common themes related to the experience within the CRN role:

1) Role isolation
2) Lack of support and understanding
3) Line management and role set up
4) Training and development

Role isolation

This was reported across four empirical papers and echoed previous anecdotal reports. In their initial study Hill and MacArthur (2006) reported that 58% (29/50) of CRNs felt isolated in their role and this was confirmed in their follow up study (MacArthur et al 2014). Adopted strategies to overcome this included discussion with clinical colleagues, interacting with other research nurses and seeking line management support. For some isolation was linked to lack of interaction with clinical colleagues and poor understanding around the CRN role. CRNs felt they were perceived as a minority group (Spilsbury et al 2012) who held a “cushy Monday to Friday nine to five job” (MacArthur and Hill 2006: 44). Feelings of isolation impacted their motivation which was felt to further impact patient recruitment rates (Spilsbury et al 2012). This was confirmed by MacArthur et al (2014: 42) with one CRN commenting it was “hard to maintain motivation and enthusiasm”. Feelings of isolation also impacted line management structure especially when not a nurse (MacArthur et al 2006) and resulted in a lack of

supervision to support the development of research specific skills which was seen to reduce opportunities for role development (Coulson and Grange 2012).

This theme was less prevalent within the three workforce reviews. Carrick-Sen (2007) reported only 7% of CRNs felt isolated and Simpson (2006) identified it as a recurring theme throughout the review but gives no further information. Edwards (2008) does not refer to it being raised. However, her review does identify that a three monthly CRN forum meeting was held which everyone within the workforce was able to attend. This may therefore help to explain why role isolation was not identified as a concern of these CRNs.

Lack of support and understanding

Lack of support from clinical colleagues and failure to understand the CRNs contribution to clinical care was reported (Coulson and Grange 2012). Spilsbury et al (2007) also reported numerous examples of the CRNs feeling unsupported. The study involved ward based patients and CRNs reported hostility from clinical nurses and a general lack of support towards the study. They reported that overall the trust would agree to run the trial but the ward staff would not co-operate. This was termed “consent but not co-operation” (pg 553) and sometimes led to animosity towards the CRNs and dealings with difficult characters. Co-operation from ward staff was unpredictable and could often change over time. The CRNs reported examples of clinical staff making decisions about clinical care which prevented patients being included in the study. Avoidance of patient involvement and poor compliance from ward nurses around trial procedures was felt to be related to ward staff perceptions that the study created extra work.

CRNs felt that support and understanding could be improved with better integration into clinical teams and highlighted possible strategies (Coulson and Grange 2012). These included helping out in ward areas and involving themselves in clinical care (Spilsbury et al 2007) as well as raising the profile of CRNs so that trust staff better understood the role and relevance to patient care (Coulson and Grange 2012).

General recommendations are also made at the end of some reports to facilitate an improvement in the support and understanding behind the role. These include identifying nurse managers for all CRNs, streamlining recruitment processes (Edwards 2008) and exploring new ways of working to maximise the interface between clinical nursing and research and appointment of a senior research nurse manager to oversee the CRN workforce (Carrick-Sen, 2007).

Line management and role set up

Three of the empirical studies reported on the difficulties that CRN faced with line management arrangements (MacArthur and Hill 2006, Coulson and Grange 2012 and MacArthur et al 2014). In their initial study MacArthur and Hill reported that only 17% (12/72) of CRNs were line managed by a clinical nurse with 43% (31/72) being line managed by a doctor and 40% (29/72) by the Directorate Manager; this had increased in their later study with 71% (65/92) being line managed by a nurse and the remainder by a doctor. Coulson and Grange (2012) reported disparities concerning line management and listed various post holders who could be responsible for this including clinical matrons, Lead CRN, Research & Development (R&D) Manager and consultants. Some CRNs struggled to identify their line manager and made comments including they didn't "feel managed in any practical sense" and "the support is there but at a distance" (MacArthur et al 2014: 42).

There was inconsistency in how the CRNs were employed. MacArthur and Hill (2006) reported that only 26% (19/72) were wholly employed by the trust with the remainder being employed through a variety of routes including the university (17%, 12/72)), a research charity (18% 13/72) or other non-specified employer (39%, 28/72). In addition 65% (47/72) were on fixed terms contracts in the range between three months to four a half years. They identified a lack of honorary contracts being in place for 56% (20/36) of CRNs so implying a possible omission for this governance requirement. In their subsequent study 65% (70/108) of CRNs were wholly employed by the trust and 34% (37/108) by the university. An honorary contract was only missing for 10% (4/40) of the CRNs, demonstrating some improvement.

Disparity around line management and professional responsibility of CRNs was also reported with just over 50% (numbers not stated) reporting to both Consultant and nurse manager (Simpson 2006). This was felt to be unsatisfactory with comments of “I feel my nurse manager is not aware of my job” and “my nursing line manager has no research background”. This arrangement was seen as partly responsible for the feelings of isolation within their role. In the review by Edwards (2008) 25% (13/52) CRNs responded that they had no line manager. Of those who did, 43% (17/39) of these were nurses and 52% (20/39) were a consultant or service manager. Carrick-Sen (2007) reported similar findings with 46% being line managed by a nurse or midwife and 23% by a medical colleague. However, line management arrangements of 30% of the workforce were not stated.

Looking at role set up, a further lack of consistency was identified. Simpson (2006) found that CRN posts were funded from a variety of sources with 12% reporting they had no contract and 12% reporting they had no job description; it was suggested this may be linked to those who had no nursing line manager. The majority of CRNs were an F grade (29%) or G grade (43%) which generally equates to band 6 and 7 as also identified by Carrick-Sen (2007). Agenda for Change was ongoing at the time of the review by Edwards (2008) and this appears to have led to some discrepancies in the banding of some CRN posts. For 79% of CRNs the outcome had been a band 5 level for their post despite the fact that they had been a mixture of grade E, F and G posts. Although Edwards (2008) found that 95% of CRNs had a job description there was no consistency in the competency between different bands, a factor which was felt to have been exacerbated by the Agenda for Change review process.

Contracts were also explored by Edwards (2008) who reported a combination of permanent (52%) and fixed term (38%) with the majority employed by the NHS (83%). Simpson (2006) identified that 54% were employed on an NHS contract and that - although 19% were employed by the university - only 2% stated they had an honorary contract.

Training and Development

Training around induction and continuing professional development (CPD) was inconsistent across the three empirical studies (MacArthur and Hill 2006, Coulson and Grange 2012, MacArthur et al 2014). In their initial study, MacArthur and Hill (2006) identified that only 50% of CRNs had attended an induction programme when starting their role and this had dropped to 36% in the subsequent study ten years later (MacArthur et al 2014). It was felt that the latter figure may be skewed by those who had been in post longer but closer inspection still found that only 46% of newly employed CRNs had attended an induction programme. The 54% that had not were all appointed by the university. It was felt that this lack of induction may explain the reason why CRNs are to some extent “hidden” (pg 44) in the organisation as they are not identified at the start of their employment. Ongoing professional development was also highlighted as an issue with MacArthur and Hill (2006) reporting that only 64% had attended mandatory training in the previous 12 months. Coulson and Grange (2012) identified a need for better support of training and professional development. They reported that CRNs were uncertain around opportunities for career progression, a concern also identified by MacArthur et al (2014) who identified that CRNs lacked a career framework with many feeling that their roles had expanded without appropriate recognition and reward.

In the workforce reviews the authors reported that attendance at induction programmes was high with rates of 93% (Edwards 2008) and 71% (Simpson 2006). Both reviews identified a wide variety of possible research specific training programmes with a range of attendance rates across the CRN workforce. Simpson (2006) listed training options such as research governance and good clinical practice training with attendance rates ranging from approximately 15% to just fewer than 80%. Carrick-Sen (2007) found that 25% of CRNs had never undertaken GCP training despite regularly taking consent for participation in research studies. Edwards (2008) also identified a range of research training programmes but attendance appears lower at rates of between 10% and 40%. In addition, Simpson (2006) also identified a variety of clinical skills training available with a wide range of attendance rates between

approximately 5 - 60%. Further information regarding specific role requirements to explain this range does not seem to have been obtained.

Lack of career development and a career pathway was a consistent theme across all 3 reviews, each of which included within their recommendations that this should be addressed and a clear career structure be developed for all CRNs.

Summary

Within this section I have aimed to review the current literature on the experience of CRNs within their role and identify the themes. A theme has been defined as “an idea that can be seen running through several responses” (Harding, 2013: 6). Although there was consistency within the reviewed papers of the 4 identified themes, caution should be used when making generalisations concerning the CRN workforce due to the small numbers of papers available to review. However, themes such as role isolation and a lack of support and understanding are additionally highlighted in some anecdotal reports or personal accounts so giving further credibility to these (Kenkre and Foxcroft 2001, Gordon 2008).

2.4.2. Review question 2: What current workforce structures are in place?

Within the empirical studies, Hill and MacArthur (2006) describe two consecutive studies across the same organisation which were carried out a year apart. The article appears to be the first published article of a UK CRN workforce review. The initial study identified 108 CRNs working across their organisation who were then all sent a postal questionnaire. The second study used the same population of which 104 were sent the questionnaire. Response rates were 72% and 48% respectively. The authors of this study carried out a further questionnaire study in 2012 to compare the findings across all 3 studies (MacArthur et al, 2014). The response rate was 58% (108/186). Both reviews revealed that the majority of the workforce was appointed at a grade F or G (pre

Agenda for Change) and the majority of CRNs had a job description. The reviews did not examine how the CRN roles had been structured within the research or clinical teams. The impetus for the initial two consecutive studies reported by MacArthur and Hill (2006) was the creation of a senior CRN post and the establishment of a Clinical Research Facility (CRF). However, no information was provided on the support this gave to the CRN workforce.

Coulson and Grange (2012) identified 36 CRNs working across a variety of clinical directorates. They were supported by a part time lead CRN at band 8b level and a part time lead CRN at band 7 level. However, no further information was provided on the structure of the CRN workforce.

Ledger et al (2008) describe a project aimed to implement a framework to co-ordinate the employment, management and development of CRNs within a large acute NHS teaching trust. Led by a working group they identified 100 CRNs working within 9 clinical care groups across 5 hospital sites and the CRF. The working group nominated one of these to be the Lead CRN who would be available for advice at least one day a week. The framework was piloted in a research active directorate and aimed to introduce consistent procedures for job descriptions, recruitment, induction, professional development and a competency document for research skills. The pilot highlighted the complexity of the CRN role and the need for a dedicated Lead CRN. Following the pilot the framework was implemented and the Lead CRN role was made a substantive post with the remit that it included responsibility for the CRN workforce across the trust. This has ensured that the recruitment, employment and professional development of CRNs occurs in a more cohesive manner. This appears to be the only published paper describing a CRN workforce review and restructure.

Carrick-Sen (2007) carried out a review of all nurses working in a research capacity within an NHS acute trust. Within this 94 CRNs were identified and a questionnaire response rate of 77% (72/94) was achieved. No further information regarding whether the CRN roles were structured within clinical or research teams was given. However, the review did identify difficulties with the

work environment with 68% sharing an office and 39% sharing a desk. The CRNs identified ‘work environment’ as the most difficult aspect of their role.

Simpson (2006) led a review of the CRN workforce using a questionnaire structure based on the reviews reported by MacArthur and Hill (2006). Here numbers were smaller with a total of 51 full time post holders and 25 post holders who had research as a secondary remit within their role. The workforce had a diverse range of experience and job titles and worked across a variety of clinical areas. Edwards (2008) identified a workforce of 60 CRNs but only 55% (33/60) had research as the main remit of their role.

Summary

Within this section I have aimed to review what CRN workforce structures are in place. Only 3 organisations have published on the structure of their workforce and I was able to identify a further 3 unpublished reports. The majority of these were carried out 10 years ago. With ongoing growth in the CRN workforce and development of the national research infrastructure within that time, caution should be used when making generalisations from these reports. However, they do provide a background to this with some early examples of how some organisations initially structured their workforce and the issues encountered.

2.4.3. Review question 3: What is the experience of other research staff concerning the CRN workforce?

No empirical papers or unpublished articles were identified that explored this issue.

Within the workforce reviews there were two additional themes.

The aim of this search had been to identify whether other health professionals had published on their interaction with the CRN workforce. However, an in-depth literature search did not reveal any publications and the author was not aware of any additional themes identified

Leadership

The importance of effective leadership was suggested within the workforce reviews. The catalyst for initiation of the review reported by Edwards (2008) was the appointment of a research co-ordination and training manager to identify and oversee the workforce; similarly, the review by Carrick-Sen (2007) recommended the appointment of a senior research nurse manager to take on this role. Simpson (2006) reported that the review had shown that nurses and midwives in research do not always have clear links with the nursing / midwifery structure so do not have the opportunity to influence policy or develop leadership skills. She therefore recommended that they should be encouraged to develop a leadership role to input at a strategic and operational level.

Research activity

The reviews by Simpson (2006) and Edwards (2008) explored the nature of the studies on which the CRNs were working. Both reviews demonstrated that they were working on a variety of research projects both commercial and non-commercial (but with a greater amount of commercial activity running clinical trials of a medicinal product). Both reviews highlighted the very small amount of nursing research that was being done. Edwards (2008) explored this further and found that only 27% (14/52) had the opportunity to conduct their own research with the main barriers being time and funding.

2.5. Discussion

This review has found a lack of studies looking at the structure of the CRN workforce and the experience of CRNs within their role. Therefore, further high quality research is needed in order to provide greater understanding concerning both of these areas. However, a number of key issues have emerged from the findings of this review which do provide some insight and understanding relating to the aims of this thesis.

There appears to be a general lack of understanding concerning the CRN role. This can impact how research is perceived within the clinical environment and how much support the CRNs receive from their clinical colleagues. Spilsbury et al (2007) gives a comprehensive insight into the reality for CRNs of running their study within a ward environment. However, the study was completed over 10 years ago and only includes the views of 9 CRNs. The remaining papers offer a small amount of information as to the experience of CRNs but this is limited as the aim of most of the papers was a general review of the workforce and not to examine specific issues within it. Line management arrangements for CRNs have also been identified as a consistent theme across the published and unpublished papers. Lack of a robust process to oversee and line manage post holders may contribute further to other themes identified such as role isolation, lack of support and lack of personal and career development. Training and development also appears to take place in an inconsistent manner leading to CRNs potentially lacking key skills for their role in areas such as research governance.

Ledger et al (2008) have demonstrated the benefits to be gained when a structured consistent process is implemented to oversee and support the CRN workforce. By initially taking steps to understand the issues faced and implementing a co-ordinated framework, they were able to demonstrate the benefits this brings in terms of better co-ordination of the running of research studies and support of the CRN workforce. However, as mentioned above this work was carried out over 10 years ago and so the picture may have changed within this one organisation.

CRNs appear to be self-motivated in their role especially in their attempts to overcome challenges such as role isolation. Spilsbury et al (2008) demonstrate the steps that some CRNs go to in order to facilitate the integration of their role alongside their clinical colleagues. However, in terms of gaining a greater depth of understanding, the focus group would need to be repeated within other CRN research teams to truly understand the challenges they face.

Despite the rapid growth in the size of the national CRN workforce, there is only speculative literature on the size of this workforce. The three unpublished reviews give an indication of the set up within the relevant organisations. However, these are isolated reviews and not available within the public arena. They all include comprehensive recommendations on suggested actions to facilitate better support of the CRN workforce. However, they are all approximately ten years old and it is highly likely that the CRN workforce within each of the organisations will have changed in size and structure.

The review has identified some common themes of role isolation and a lack of support and understanding which are also confirmed by some of the anecdotal reports and personal accounts of the role. However, the additional themes of leadership and research activity are more sparsely represented within the literature and so may be viewed as weaker. This limits their significance and restricts researchers in their ability to make generalisations. However, it does identify these as potential additional themes which could then be explored in future research.

2.6. Summary

This review has demonstrated the sparse amount of current literature and understanding concerning the questions under review. However, it has generated some initial knowledge regarding the size of the CRN workforce within some NHS trusts and the challenges faced by CRNs in the conduct of their role. Within this it has identified areas which should be examined in greater detail in order to gauge a better understanding. It has given an overview of the difficulties faced by a nursing workforce which has seen a large amount of

growth since the beginning of this century and how some organisations have attempted to support this.

Building on the findings of this review, the following chapter will now define the aim of the study and research questions within this. It will also describe the framework used to structure the data collection.

Chapter 3: Study aims and theoretical framework

3.1. Introduction

This chapter will discuss the overall aim of the study and the research questions relating to this. It will also describe the framework which has been used to structure the data collection and the rationale for its use.

3.2. Overall research question

How is the CRN workforce is currently organised within NHS Acute trusts, what is the experience of CRNs working within acute NHS hospital trusts and what is the most effective way to structure the CRN workforce?

3.3. Research objectives

In attempting to meet this overall research question the following research objectives were considered.

- To identify acute hospital trusts which have reviewed the structure of their CRN workforce.
- To identify which acute hospital trusts have subsequently introduced a new structure.
- To explore how the CRN workforce is currently organised within NHS Acute trusts using a quality framework.
- To explore and compare the experience of Clinical Research Nurses within different organisations using a quality framework.
- To explore the experience and perception of senior research staff (R&D Directors, Lead CRN and Principal Investigators) concerning the research nurse workforce within their organisation.
- To examine the effect of re-organising the CRN workforce on NIHR targets.

3.4. Data collection framework

There was no available tool that could be used to collect data on the structure of a CRN workforce and examine attributes within it. The “Organising for Quality” framework (Bate, Mendel and Robert 2008) was identified as a helpful framework for organising data collection as the components within it matched several of the areas that had been identified within the literature review, such as education and structure, as being important to be examined within this study. This framework was originally designed to describe the factors (defined as challenges, see Figure 3.4-1) that enable healthcare organisations to achieve and sustain quality improvement. The challenges within the framework are as follows:

- Structural
- Educational
- Emotional
- Cultural
- Political
- Technology and Infrastructure

3.4.1. Origins of "Organising for Quality Framework"

Figure 3.4-1 Organising for Quality Framework (Bate et al 2008)

This framework was the result of an international study, conducted jointly by researchers from the UK and the USA, that was designed to help practitioners and researchers understand the factors and processes that enable health care organisations to achieve and sustain high quality services for their users. The existing literature had focused on a "menu mentality" (Bate et al 2008: 6) of the key success factors that equate with quality healthcare but with no understanding of how or why some organisations perform better than others. The researchers carried out in depth case studies in eight leading hospitals to give an international, evidence based outlook that focuses on the organisational and cultural processes of Quality Improvement (QI). They examined hospitals and medical centres (four in America and four in Europe) that had earned a reputation for sustained achievements in QI and performance with the aim of understanding the process of QI. The authors conclude that there are many

different paths to successful, sustained QI but the unifying features are an ability to address multiple challenges simultaneously and to adapt the strategies to the organisations own needs. They present a model (see Figure 3.4-1) of what they see as the six core challenges for organisations to achieve and sustain QI. They propose that these are problems which any organisation will need to find solutions to and if ignored will lead to disappointment and failure in their QI.

Since its development this framework has been used by other researchers to support data analysis although the data collection was not structured around the framework as it has been in this study. Krein et al (2010) carried out a study to examine QI efforts related to the prevention of central line infections. Data was collected using semi – structured interviews (telephone and in person). During the course of data analysis they found that the 6 challenges of QI as described in the Organising for Quality framework corresponded with their results and provided a useful interpretative framework for their findings. Hamilton et al (2014) used this framework to explore the QI capacity of 8 hospitals that were implementing the Releasing Time to Care (RTC) programme. Interviews were conducted with staff who worked in nursing units where RTC had been implemented. In the data analysis phase identified themes were mapped to one of the domains (called challenges within the framework) which were seen as important to the success or failure of the RTC initiative. Use of the Organising for Quality framework enabled them to articulate the QI impact of the RTC programme.

3.4.2. Rationale for use of the "Organising for Quality Framework"

This framework was chosen for this study as it offered a structure to define categories of data collection in order to answer the research questions. The challenge of structure is self-explanatory in its choice when the study was looking to identify those acute trusts that have reviewed and restructured their CRN workforce. The challenges of education, culture, emotion and politics are

all likely to have an impact when exploring the experience of CRNs and research staff. The challenge of technology and infrastructure also offers important insight into the structure of a workforce. Therefore all components of the framework - and the interactions between them - were felt likely to be relevant to the research questions being examined.

A definition of each of the six challenges is given by the framework's original authors. Within this they define "solutions" and provide an explanation for each which gives further clarity and direction for the reader around each challenge. These definitions within the framework were examined and applied to research and the CRN workforce; a modified definition for each challenge (see Table 3.4-1) was then devised and this was used as the foundation for data collection. Questions were devised for each of the challenges to examine the CRN workforce, factors related to the experience of the CRNs within the clinical environment and the organisation of research within the organisation.

Table 3.4-1 Practical application of the 'Organising for Quality' framework to a clinical research setting. Adapted from Bate et al 2008.

Challenge	Original definition in framework	Definition applied to CRN workforce
Structure	Structuring, planning and co-ordinating the quality and service improvement effort, and embedding it within the organisational fabric.	Structuring, planning and co-ordinating the Clinical Research Nurse workforce, and embedding it within the organisational fabric to ensure high quality research governance and patient safety.
Cultural	Building a shared understanding, commitment and community around the improvement process	Building a shared understanding, commitment and community around research and the CRN workforce
Education	Embedding and nurturing a continuous learning process in relation to quality and service improvement issues, including both formal and informal mentoring, instruction, education and training, and the acquisition of relevant knowledge, skills and expertise.	Embedding and nurturing a continuous learning process for the CRN workforce in relation to high quality research governance and patient safety including both formal and informal mentoring, instruction, education and training and the acquisition of relevant knowledge, skills and expertise.
Emotional	Energising, mobilising and inspiring staff and other stakeholders who want to join in the improvement effort by their own volition and sustain its momentum through individual and collective motivation, enthusiasm and movement.	Energising, mobilising and inspiring staff and other stakeholders to be involved in processes to ensure high quality research governance and patient safety.
Political	Negotiating the politics of change associated with implanting and sustaining the improvement process, including securing stakeholder buy in and engagement, dealing with conflict and opposition, building change relationships and agreeing and committing to a common agenda for improvement.	Negotiating the politics of change associated with implanting and sustaining the CRN workforce, including securing stakeholder buy in and engagement, dealing with conflict and opposition, building change relationships and agreeing on a common agenda to ensure high quality research governance, support the achievement of NIHR objectives and ensure ongoing patient safety.
Technology	The design and use of a physical, informational and technological infrastructure that improves service quality and the experience of care.	The design and use of a physical, informational and technological infrastructure that improves research governance and the experience of patients who take part in research studies.

3.5. Summary

This chapter has laid out the study aim and questions to be explore within this study. It has described the framework that has been selected to structure the

data collection and given rationale for its use. The study methodology within the phases of the study will be described in the next chapter.

Chapter 4: Research design and methods

4.1. Introduction

This chapter presents the overall study design to meet the aims and research questions presented in the previous chapter, details the two phases of the project and also explains the approach taken to sampling decisions, data collection methods and data analysis.

4.2. Study Design

The study itself was designed and conducted in two phases which are the focus of the following chapter. Appendix 8 provides a timeline for the phases of the study.

Phase 1a: a national online survey of NHS acute hospital trusts who were involved in recruiting into research studies was carried out. It aimed to identify the Lead CRN at each NHS acute trust or someone within the R&D Department who was responsible for the CRN workforce. A survey tool was developed using the "Organising for Quality Framework". This survey included the following:

- 161 Acute NHS Hospital Trusts in England
- 14 Scottish Health Boards
- 1 Acute Trust in Wales
- 1 Acute Trust in Northern Ireland

The survey was distributed via Survey Monkey, an online survey development tool.

Phase 1b: statistical analysis of NIHR recruitment figures over a six year period (2010 – 2016) for all organisations that completed the survey.

Phase 2: Case studies of four organisations selected from those that took part in phase 1a. Data collection comprised of three or four semi-structured interviews and a focus group at each organisation.

4.3. Methodology

The methodology describes the research design, data collection tools used and the approach to data analysis. Underpinning the methodology is the philosophical stance which focuses on the differences between the quantitative research paradigm, which is generally associated with the philosophical traditions of positivism and the qualitative research paradigm, most commonly allied with post positivist philosophy (Polit et al 2001) or Interpretivism. Morgan (2007) describes these paradigms as epistemological stances with “distinct belief systems that influence how research questions are asked” (pg 52) and “worldviews or all-encompassing ways of experiencing and thinking about the world” (pg 50).

Positivism is a philosophy that uses reason and rational thought to explain phenomenon. It assumes a stable, observable reality that can be measured and observed, and is derived in a systematic, rigorous way (Bruce et al 2009). The ontological position is that there is only one truth that is an objective reality that exists independent of human perception (Sale et al 2002). Within this epistemological stance the investigator and subject are independent variables which do not influence each other. One of the primary characteristics is that the researcher takes an objective distance from the phenomena so that the description of the investigation can be detached and undistorted from emotion or bias (Davey 1994). Others refer to this as researchers withholding their beliefs in order not to contaminate the data (Larkin et al 2014).

A contrary or alternative view is interpretivism. This grew from the writings of Kant who proposed that perception relates to human interpretation and Dilthey who emphasised the importance of understanding and studying lived experience (Ormston et al 2014). The ontology position is that there are multiple realities or truths. Epistemologically, there is no access to reality independent of our minds so that the investigator and subject are interactively linked. The data has no existence prior to the activity of the investigation and ceases to exist once the activity is complete. This data aims to interpret actions and understand

behaviour. It uses language and looks at the what, how and why of a phenomenon (Green and Thorogood 2009).

4.3.1. Mixed methods

A combination of both of these approaches, known as a mixed methods design, provides more evidence for studying a research question and can access knowledge or insights unavailable when data collection methods are undertaken independently (O'Cathain et al 2007). Cresswell and Piano Clark (2011) refer to it as "multiple ways of seeing and hearing and multiple ways of making sense" (pg 4) whereas Johnson et al (2007) refers to it as "the third major research approach" (pg 112). In seeking to answer the research question and aims above it was decided that the mixed methods design was most appropriate

Within this discussion it is pertinent to briefly consider the difference between multiple method research and mixed methods research in order to offer some clarity and confirmation in the choice of mixed methods. The terms are easily confused and mistaken as synonymous. However, there is a general agreement that there are differences between the two (Johnson et al 2007). As previously explained a mixed methods approach uses both qualitative and quantitative data collection methods. However, multiple or multi method research involves data collection using two methods from the same paradigm, such as interviews and focus groups (Andrew and Halcomb 2009). Important aspects of mixed methods research include its consideration from initial philosophical underpinnings, through data collection, analysis and interpretation as well as the mixing of data (Halcomb and Hickman 2015). In addition an important component is also the mixing or triangulation of data (Bryman 2006).

Mixed methods research has become a common component of research within the health service (O'Cathain et al 2007). The main purposes for combining methods in studies have been highlighted by O'Cathain (2007). These include:

- Complementarity – methods are used to address different aspects of the same question.

- Expansion – methods are used to address different questions.
- Development – one method is used to inform the development of another.
- Confirmation – the results of the two methods converge.

This study utilised mixed methods to address the need for complementarity and confirmation. Use of the 'Organising for Quality' framework to structure the collection of data allowed subject areas to be examined for each phase of the study within the six challenges; the findings could then be applied to the study aims during the analysis. For example, for the challenge of "Culture" the survey asked "Do your nursing colleagues understand the CRN role?" whereas within the interview participants were asked "What is the understanding of the research nurse role?" Within the survey, statements were provided concerning the importance and value of research within the organisation and respondents were asked to rate their agreement on a 5 point Likert scale. Within the interview participants were asked "What is the importance associated with research across the organisation and how much value is put on it from a nursing perspective?" Data from these would then be used to help interpret factors around the experience of CRNs. This allowed the researcher to address different aspects of the same question in order to determine whether the results converged.

Within mixed methods a research problem is examined using different methods of data collection to gain a more complete picture (O'Cathain et al 2010). Both sets of data can then be analysed using a process known as "Triangulation". It was Denzin (1978) who first outlined how to triangulate research methods and described 4 types including:

1) Data Triangulation – using a variety of sources within a study.
2) Investigator Triangulation – use of different researchers.
3) Theory Triangulation – use of multiple perspectives and theories to interpret results.
4) Methodological Triangulation – use of multiple methods to study a research question.

This study uses methodological triangulation through the use of a survey, interviews and focus groups within a case study presentation. When the methods are integrated a process of interpretation takes place when the data from each method is initially analysed separately and the findings are integrated (O'Cathain 2007). Each set of data on its own provides part of the story for the research question, but together they contribute to a broader understanding of the research question (Farmer et al 2006).

According to O'Cathain et al (2010), triangulation enables the findings to be explored for the following:

- Convergence – do the findings agree?
- Complementarity – do the findings offer complementary information on the same issue?
- Discrepancy – do the findings contradict each other?

Farmer et al (2006) add an additional category of "silence" to capture whether one set of data covers a theme whereas the other remains silent. This would be important as it may demonstrate different perspectives on the same point under discussion.

When considering the philosophical stance within mixed methods, authors refer to pragmatism as it is not committed to any one system of philosophy and reality but "draws liberally from both the quantative and qualitative assumptions" (Cresswell, 2009, pg 10). It can be viewed as a set of philosophical tools that can be used to address problems (Biesta 2010). Pragmatism allows the researcher to use a combination of whichever methods are needed to find answers to the research questions. Authors emphasise that instead of focusing on methods, researchers initially emphasise the research question and then use all approaches available to understand the issues within it (Morgan 2007). Therefore for the mixed methods researchers, pragmatism opens the door to use of multiple methods, different worldviews and different assumptions gained from different forms of data collection and analysis (Cresswell, 2009).

Therefore, within this study a pragmatic approach enabled the researcher to initially consider the research questions to be explored both nationally within the survey and locally within the individual case studies. This then led to the use of a variety of data collection methods such as open and closed questions within the survey, interviews and focus groups in order to gain a broad understanding of the issues being explored.

4.3.2. Case study design

Case study design was chosen as the method for phase 2 of data collection as it allows the researcher to "retain holistic and meaningful characteristics of real life events" (Yin, 2009, pg 4). It also enables researchers to empirically investigate and gain in depth, in context understanding of a phenomenon from key informants who were directly involved in the activities being studied (Yin 2009). One of the study aims was to "explore and compare the experience of research staff within different organisations". By choosing this design the researcher was able to directly speak with CRNs and those involved with research (the key informants) across different organisations (the context) in order to explore their experience (the phenomenon). By collecting data in real life settings, case studies provide thick descriptions which enable others to make a judgement about the relevance of the findings to their own setting (Taylor 2013). This would then allow analysis of themes across the different participants within each of the case studies. As confirmed by Baxter and Jack (2008) the goal of data analysis within a case study is not to analyse individual data sources independently but to combine the data from all sources in each setting and then across settings. By interviewing the same groups of staff across different organisations the researcher was able to examine themes for consistency or differences. Yin (2009: 106) refers to "guided conversations" rather than "structured queries" when carrying out interviews within a case study. This allows the interview to be fluid as opposed to rigid. Additional flexibility allowed the researcher to discuss single issues (such as CRN experience) across all study groups.

4.4. Research methods

The following section presents the different methods used to collect the study data.

Quantitative data collection

The collection of quantitative data was planned in order to obtain data regarding the workforce size and structure in as many acute trusts as possible. In recent years organisations have developed a senior CRN post to take overall responsibility for the workforce. This post of a Lead CRN will lead on the support and development of the total CRN workforce. It was therefore anticipated that within organisations where this post had been developed, the individual would have the greatest awareness and knowledge of their CRN workforce.

A structured questionnaire was developed that asked participants to provide information on workforce size and an overview of experiences and challenges faced by individual CRNs. Questions were structured and 5 point Likert scales were also used to uncover strength of opinion. Some questions included an open comments box to allow participants to expand answers.

In order to approach all Lead CRNs within the target populations the questionnaire was sent as an online survey using “Survey Monkey”. This allowed the researcher ease of access to the planned UK wide study population. Known advantages of electronic surveys include the low cost (Scott et al 2011) and ease of data analysis as simple descriptive statistics are usually embedded providing concurrent analysis for researchers (Evans and Mathur 2005). Disadvantages include access to up to date email addresses and a possible lower response rate compared to postal surveys (McPeake et al 2014). Problems with incorrect email addresses were overcome as the researcher was part of an active national group of Lead CRNs which provided the initial batch of contact details after relevant approvals. For those organisations where the Lead CRN was not known, the R&D department was directly approached by the

researcher so preventing the possibility of incorrect contact details. Results from the survey were analysed using descriptive and inferential statistics and these processes are described in a later section of this chapter.

Qualitative data collection

Including qualitative data was necessary in order to uncover a depth of understanding concerning individuals within the organisation to add richer data to describe the experience of the research process. A growth in the size of the workforce has led to some organisations reviewing and re-structuring their teams. A secondary aim of the study was to identify which organisations have performed a review and carried out changes within the CRN structure based on the results. Therefore a case study approach was adopted in order to examine two organisations that had reviewed and restructured their CRN workforce and two that had not. Data collection was in the form of focus groups and interviews with different members of the research team as it was important to directly hear the voice of those involved.

4.5. Phase 1: Online questionnaire

4.5.1. Development of phase 1 survey tool

The objectives of the questionnaire are:

1) To identify the acute hospital trusts that have reviewed the structure of their CRN workforce.
2) To identify which acute hospital trusts have subsequently introduced a new structure.
3) To explore how the CRN workforce is currently organised.

4.5.2. Expert Review Panel

An “Expert Review Panel” was set up by the Researcher to gain feedback on the questionnaire structure and content. Eight panel members who were nurses experienced in clinical research were selected (see appendix 9 for summary).

They were sent a PDF copy of the questionnaire and a review template which they were asked to complete (appendix 10). This included questions on their overall opinion of the questionnaire as well as content, layout and the length of time to complete. Responses were analysed and adjustments made.

It is acknowledged that expert groups may have their limitations due to the subjective nature of their set up by the researcher. However, it remained important in the design of the questionnaire to gain the views and feedback from experienced peer colleagues as to the approach being taken. Completion of the template did ensure a consistent approach to their review and it was felt by the researcher that valuable feedback on the questionnaire design and content was received.

4.5.3. Alterations to the questionnaire

1) Some felt it was too long which may affect completion rates. This was considered but the majority of questions remained as they were considered important to the study aims.
2) Average time to complete was 20 and 30 minutes. Therefore information added to inform participant's completion may take up to 30 minutes.
3) Suggestion that further instructions for completion of the survey should be given.
4) Suggestion that additional research support roles including Quality Assurance Manager should be added.
5) Concern that not all requested information would be available. This was acknowledged as a possibility but not felt to be a reason for removal of some questions.
6) Some felt that easy questions were towards the end and that these may be missed because of the length of the survey. These were therefore moved to near the beginning.
7) Suggestion made for addition of other research relevant training requirements so added.

4.5.4. Questionnaire Pilot

Once finalised it was necessary to pilot with a small group of senior CRNs who would be similar to the main study population. The pilot was carried out towards the end of 2013. At this time the National Cancer Research Network (NCRN) had been set up for 12 years and comprised 32 Research Networks each led by a Network Manager who over saw a large team of staff, mainly CRNs. This had marked the beginning of an identifiable structure within which CRNs could be based and offered the opportunity to pilot the survey within a small number of the main study population.

The NIHR Co-ordinating Centre in Leeds was approached for permission to contact the NCRN Network Managers. The request to take part in the pilot was then included in their regular newsletter and a link to the survey was provided (appendix 11). The network managers were also due to attend a regular national update meeting. Therefore a presentation about the study and intended pilot was prepared and sent to the NIHR Co-ordinating Centre and was delivered during the meeting. The survey ran throughout December 2013 and early January 2014.

4.5.5. Pilot Results

The pilot study was analysed and a report produced. A summary report was sent to the NIHR co-ordinating centre to distribute to the network managers. A response rate of was 65.5% (21/32) was achieved. All questions were completed by 44% of respondents (14/32) but all surveys contained answers to at least 50% of questions unless they were optional and linked to a previous question.

The pilot study gave a comprehensive overview of the CRNs working within the NCRN structure and identified twelve issues that were of particular relevance to the main study. These are summarised in appendix 12.

4.5.6. Alterations following the pilot

Changes were made to the questionnaire based on feedback from the NCRN Managers and from observations related to how it had been completed. These included:

1) The original survey used the term CRN for Clinical Research Nurse. The networks were in a state of transition and the term for the new structure was the Clinical Research Network - abbreviated to CRN. Therefore due to some confusion within the main questionnaire the abbreviation RN was used for Research Nurse.
2) In the pilot, questions were clustered within each challenge of the framework. The majority of respondents completed at least 50% leaving some challenges missed. Within the main questionnaire, questions were mixed around with the demographics and structure questions placed towards the beginning.
3) The pilot asked “Does your organisation have any new IT developments that have been introduced over the last 2 years?” in order to determine whether any organisation wide IT developments, such as electronic patient records, had been introduced. Many interpreted this as being related to research and so referred to research related technology. In the main survey the question was changed to “Has there been any organisation wide IT developments that have been introduced over the last two year? (for example electronic patient notes).

The finalised questionnaire comprised of 56 questions which included both open ended and closed questions. These were uploaded onto Survey Monkey with an introduction to the survey on the first page. See appendix 13 for a copy of the full survey.

4.6. Data analysis – Phase 1a and 1b

Analysis used both descriptive and inferential statistics. Descriptive statistics allow data or samples to be described in a succinct and meaningful way but do

not allow any conclusions to be drawn about the data or sample. Typically descriptive statistics are simple numerical or graphical summaries of data and include measures of central tendency (mean, median, and mode) and measures of spread such as range, quartiles and standard deviation (Harris and Taylor 2010).

Inferential statistics allow inferences to be drawn from the sample analysed about the population of interest. This is achieved by applying statistical tests to the data, such as Chi-squared test (Plichta and Garzon 2009). Combining both descriptive and inferential statistics allows large amounts of data to be described and relationships within the data or to a larger population shown concisely (Creswell 2009).

4.6.1. Phase 1a study population

The initial target population for the survey was planned to be University Hospital Trusts listed within the Association of United Kingdom University Hospitals (AUKUH) as they were known to responsible for a large amount of study recruitment. In 2011/12 the average baseline recruitment for an AUKUH Trust was 5799 patients compared to a national average of 1463 (Watson 2013). On closer inspection and following communication with a Senior Policy Officer within the AUKUH it was found that their membership did not include all current university hospitals so was not a true reflection of all research active organisations.

Following this a list of acute hospital trusts recruiting into NIHR portfolio studies was examined. It identified 161 research active NHS acute hospital trusts in England which were then chosen as the main population sample for data collection. Despite a lack of consistency in UK healthcare systems the study aimed to be as inclusive as possible. Therefore all 14 Scottish Health Boards were included as well as one organisation each from Wales and Northern Ireland. This gave a total study cohort of 177 possible organisations.

4.6.2. Identification of Lead CRN at each site or individual responsible for CRN workforce

Lead CRNs across all potential organisations were identified through three routes in the following sequence:

1) Membership of a national organisation of Lead CRNs. This was established to provide sharing of ideas and peer support for those in the role. Membership had grown and at the time of planning the survey rollout it stood at approximately sixty nurses of which the researcher was one.
2) NHS R&D Forum website list of R&D Managers across England who were individually contacted and asked to provide the name of their Lead CRN or someone responsible for the CRN workforce.
3) If step was not successful or the website information was incorrect or missing, individual acute trust websites were viewed in order to identify telephone contact details. Organisations were then individually telephoned with the aim of speaking to R&D Manager or appropriate person.

From a total of 177 organisations, a Lead CRN or individual responsible for the CRN workforce was identified in 144 organisations. This comprised 135 out of a possible 161 acute NHS trusts in England and seven out of a possible fourteen Scottish Health Boards. It also included one organisation in Wales and one in Northern Ireland. Within England there was a good representation across all five trust types and therefore the missing thirty three organisations did not prevent a representative sample. Invitations were sent out in five groups as contact details were identified. Reminders were sent via the Survey Monkey site on two further occasions at fortnightly intervals. The survey ran from April to June 2015.

4.7. Phase 1b: NIHR recruitment figures

NIHR portfolio recruitment figures were obtained in order to examine whether re – organisation of the CRN workforce had any effect on the amount of participants recruited into all studies. The NIHR was contacted in order to obtain as full a data set as possible as only recent recruitment figures were available in the public domain. The researcher was able to obtain full recruitment data for all participating organisations from October 2010 to September 2016 (annual NIHR recruitment year measured from 1st October until 30th September).). Annual data for each organisation was as follows:

- Total number of Interventional studies
- Total number of Observational studies
- Total recruitment numbers into Interventional studies
- Total recruitment numbers into Observational studies.

Additional data about the CRN workforce size was obtained from the researchers' survey of the workforce for 2014/15 but was not available for other years.

NIHR recruitment figures were analysed using the Statistical Package for Social Sciences (SPSS), version 23. Choice of statistics for data analysis is determined by previous decisions such as the method of analysis, level of measurement of the variables and complexity of the research objectives (de Vaus, 2002a, b). In order to address the research objectives of the current study, data were analysed using descriptive, univariate and bivariate procedures.

A generalised estimating equations (GEE) modelling approach was used to ascertain whether the number of studies (intervention or observation) and number of people recruited into those studies was explained by trust type, year and whether the trust had undertaken a review. GEE was used specifically to account for within-trust clustering (year nested within trust). The models were

analysed with SPSS using the command GENLIN and subcommand REPEATED (Field 2009).

The 2014/15 data were also modelled using the following explanatory variables: trust type, review and number of CRNs (grouped into quintiles: 0-9, 10-15, 16-25, 26-50, 51 and over). On this occasion the REPEATED subcommand was not required because there was only one year of data. Both models assumed that the number of studies and people were generated from a Poisson distribution (Field 2009).

Test of model effects ($\chi 2$, degrees of freedom) and estimated marginal means (mean for a variable/factor having adjusted for all other variables in the model) with 95% confidence intervals are presented. A type I error (p) of less than 0.05 was the criteria used to determine whether an effect was statistically significant (or not).

Throughout the data analysis process regular meeting with a statistician were held to clarify ambiguities and ensure appropriate procedures were followed.

4.8. Phase 2: Case Study

Four case studies were purposively sampled and invited to participate in phase 2 of the study. Purposive sampling means members of the sample are chosen with a purpose: to represent a “type” in relation to key criteria (Ritchie et al 2014). This allows the researcher to use their personal judgement for choosing the cases and selection criteria that will allow the research questions to be answered and objectives achieved.

The aim of the case study was as follows:

- To explore and compare the experience of research staff within different organisations using a quality framework.

- To explore the experience and perception of senior research staff (R&D Directors, Lead CRN and Principal Investigators) concerning the research nurse workforce within their organisation.

4.8.1. Identification of participating organisations

Within the phase 1 of the survey, respondents were asked whether they would consider taking part in phase 2 of the study. Four sites were identified from organisations who agreed and were segregated into two groups depending on whether the CRN workforce had been reviewed. From each group, two organisations were selected with matched criteria linked to (a) workforce size and (b) NIHR recruitment numbers as shown in Table 4.8-1. Identification of case study 4 was more problematic than for case studies 1-3. The initial and second choice organisations were better matched from a recruitment number perspective but when approached were unable to take part. Therefore the organisation for case study 4 was selected as it matched the workforce size of the criteria for its control which was case study 1. However, the NIHR recruitment figures were not as well matched as the researcher would have ideally liked.

Table 4.8-1 Characteristics of Trusts in case studies, including clinical research nurse workforce and recruitment number as reported for the year 2014-2015 (NIHR 2015).

Case Study	CRN workforce reviewed	CRN workforce size		NIHR recruitment numbers (14/15)	
		Nurses	Quartile	Participants recruited	Quartile (Range 469 – 23,187)
1	Not reviewed	15	Quartile 1 (Bottom)	1006	Quartile 1 (Bottom)
2	Reviewed	120	Quartile 4 (Upper)	7786	Quartile 2
3	Not reviewed	130	Quartile 4 (Upper)	9145	Quartile 2
4	Reviewed	23	Quartile 1 (Bottom)	6685	Quartile 2

4.8.2. Planning of data collection visits

Lead CRNs were contacted to inform them they had been selected for phase 2 of data collection and to confirm agreement to participate. Information was provided regarding structure of data collection and information sheets were sent for each group of study participants (see appendix 14 to 17). The Lead CRNs was asked to identify the following participants to take part in an interview:

- Principal Investigators currently recruiting into NIHR portfolio studies
- R and D Director

They were also asked to identify approximately five CRNs to take part in a focus group and informed that they would be asked to participate in an interview.

4.8.3. Recruitment of participants

Participants had all received a copy of the information sheet prior to the day of data collection. At the beginning of each interview the researcher introduced themselves to the participants and explained their professional background. The researcher then explained the following:

- Brief overview of the study
- Progress to date
- Study rationale plus aims and objectives
- Brief overview of interview structure
- Confirmed that the interview would be recorded and transcribed.

As the study was initially defined as Service Evaluation, written consent was not sought.

4.8.4. Data collection procedures

Semi-structured interviews

The interview is the most widely used method of producing data in qualitative health research, and is a conversation directed towards the researcher's particular needs for data (Green and Thorogood 2009). Interviews are classified as to how far the researcher directs the interview. They range from structured where the interviewer follows a specified set of questions in a specified order to informal interviews which mimic natural conversations in an opportunistic manner with no structure or planning. The most commonly used types of interviews are i) Semi-structured – the researcher sets the agenda, ii) In-depth – allows the participant enough time to develop their own accounts iii) Narrative interview – the researcher facilitates the participant to tell their story.

Within this study semi-structured interviews utilised a topic guide that was structured according to the six challenges within the quality framework (appendix 18).

Questions were designed around some of the general themes within the phase 1 survey such as:

- The understanding around the CRN role and research in general.
- The interaction with clinical nurses
- The understanding from clinical staff of research requirements such as clinic space.
- Training and Education issues.

Each group had the same questions planned with slight variations to account for role differences. Data collection was planned to take place on a single day. The interviews were planned throughout the day by the Lead CRN who provided the researcher with the schedule in advance.

As described by Dearnley (2005) participants were encouraged to talk about their experiences and views through open-ended questions which aimed to

encourage depth and vitality and allow new concepts to emerge. Use of semi-structured interviews within this study ensured that participants across and within all the case studies were asked the same questions. It allowed the interviewer to focus on issues of particular importance to the research question, probe and clarify comments made by the participants and use prior knowledge to support the questioning, whilst still allowing the participant the freedom to address any issues which they deemed important (Rose 1994).

Table 4.8-2 Phase 2 Interview lengths

Case Study	Role	Length hh:mm:ss
1	Lead CRN	01:15:32
	R and D Director	00:50:23
	Principal Investigator 1	00:40:22
	Principal Investigator 2	00:44:33
2	Lead CRN	01:17:49
	R and D Manager	00:33:20
	Principal Investigator 1	00:28:15
	Principal Investigator 2	00:32:12
3	Lead CRN	01:12:15
	Head of Nursing & Midwifery Research	00:59:13
	Principal Investigator 1	00:39:59
4	Lead CRN	01:10:49
	R and D Director	01:03:59
	Principal Investigator 1	00:31:35

Fourteen semi-structured interviews were carried out across the four case studies. The order was dependant on the schedule prepared by the Lead CRN. However, the researcher had requested that the Lead CRN was interviewed first in order to gain an overview of the organisation and to give the researcher some initial information concerning items to be discussed across all participants. This occurred in all organisations except case study 4 where the Lead CRN was the second person to be interviewed.

Interviews were conducted face to face, individually and in a quiet location. Each interview was recorded using a Dictaphone and lasted varying lengths as shown in Table 4.8.2. Contemporaneous notes were also taken during each data collection visit.

Focus Groups

Including the voice of the CRNs was important as it provided greater insight to their experience working within different organisational structures. Social interaction around a topic, to gain an understanding of a group's responses to similar experiences, is the basis of focus groups (Côté-Arsenault 2013). Typically, participants present their own views and experience but also hear from other people; they listen and reflect and in the light of this may further consider their own standpoint (Finch et al 2014). They ask each other questions to seek clarification, comment on what they have heard and may prompt others to reveal more. As the discussion progresses, individual responses become sharpened and more refined and so move to a deeper and more considered perspective (Finch et al 2014). The focus group helps to facilitate people to explore and clarify their views through a group process in ways that would be less easily accessible in a one to one interview (Spilsbury et al 2007). Therefore, one of the strengths of using focus groups is the group interaction that promotes spontaneity in responses. This is seen to present more of a natural environment than an individual interview as participants are influencing and influenced by each other just as they are in real life (Krueger and Casey 2009). As confirmed by Morgan (1997: 2) "the hallmark of focus groups is their explicit use of group interaction to produce data and insights that would be less accessible without the interaction found in the group".

Each focus group included up to seven CRNs from each case studies. This allowed the researcher to gain a direct insight into their experience and provide the opportunity to reflect on and describe the reality of their role. The Lead CRN had sent the initial invite to their workforce. When the individual CRN confirmed their interest a copy of the participant information sheet was sent. The length of each focus group, banding and experience level of the CRNs varied as shown in Tables 4.8-3 to -6. Each focus group was recorded using a Dictaphone and conducted by the researcher in a quiet location.

Table 4.8-3 CRN participants in focus groups for Case Study 1

Duration: 1 hour, 23 minutes and 23 seconds				
CRN number	Role title	Band	Clinical area	Length of time in research
1	Generic CRN	6	Numerous	Not stated
2	CRN	6	Renal, Gastro & respiratory	Not stated
3	Generic CRN	6	Stroke	Not stated
4	Generic CRN	6	Mainly gastroenterology	Not stated
5	Generic CRN	6	Paediatrics, Women's & neonatal	2 ½ years

Table 4.8-4 CRN participants in focus groups for Case Study 2

Duration: 1 hour, 15 minutes and 35 seconds				
CRN number	Role title	Band	Clinical area	Length of time in research
1	CRN	6	Neonatal unit	21 years
2	CRN	6	Oncology	8 years
3	CRN	6	Generic for Research network	6 years
4	CRN	6	Clinical Research Facility	7 years
5	Research Sister	7	Clinical Research Facility	5 ½ years

Table 4.8-5 CRN participants in focus groups for Case Study 3

Duration: 1 hour, 16 minutes and 40 seconds				
CRN number	Role title	Band	Clinical area	Length of time in research
1	CRN Nurse Manager	7	Gastroenterology & Hepatology	6 years
2	CRN	6	Emergency Department & Critical care	15 months
3	CRN	6	Emergency Department & Critical care	5 years
4	Lead CRN	7	Renal	12 years
5	CRN	6	Renal	Not stated
6	CRN	6	Paediatrics	6 years
7	CRN	6	Paediatrics	4 years

Table 4.8-6 CRN participants in focus groups for Case Study 4

Case Study 4: 1 hour , 2 minutes and 15 seconds				
CRN number	Role title	Band	Clinical area	Length of time in research
1	CRN	6	Neurosciences	1 year
2	Oncology Lead CRN	8a	Oncology	3 ½ years
3	CRN	6	Haematology & Oncology	2 years
4	CRN	6	Haematology	2 years
5	CRN	6	Gastro-Intestinal	1 year
6	CRN	7	Cardiovascular	Not stated

All focus groups were conducted in a consistent manner and followed the guidance and stages as described by Ritchie et al (2014). These are as follows:

1) Scene setting and ground rules – Participants were given a study overview and ground rules to include confidentiality and allowing others to speak.
2) Individual introductions – Participants were asked to state their name, band, area of research and length of time in research. This was especially important in the larger organisations where the participants did not know each other.
3) The opening topic – this provided a general neutral topic to facilitate the beginning of the discussion.
4) Discussion – this was the main body and followed the interview schedule.
5) Ending the discussion – participants were informed when the final challenge was being discussed and this helped to signal that the focus group was coming to an end.

Following the focus group each was typed out verbatim to produce a transcript.

4.9. Analysis of phase 2 data

4.9.1. Interviews and focus groups

Data analysis of qualitative data, whether from interviews of focus groups, involves a process of labelling, organising and interpreting in order to generate a set of codes, categories or themes (Spencer et al 2014). These can then be further analysed in order to gain a deeper understanding and perspective of the participants' views. Categories or themes can be determined in an inductive or deductive way (Elo and Kyngas 2008). If there is not enough former knowledge about the phenomenon being studied, the inductive approach is recommended whereas the deductive approach is based on previous knowledge. Within this study a total of 14 interviews and four focus groups were typed verbatim to produce 18 transcripts. These were then uploaded onto the data analysis package NVIVO version 10.0. All 18 transcripts were analysed together using an initial process of cross sectional analysis. Here the researcher devises an overall and common system of labels which is applied across the whole data set and used as a means of searching for and retrieving similarly labelled chunks of data. The initial labels were the six challenges within the Q.I framework. Within this initial codes (or main themes) were identified using a deductive approach based on the researchers own knowledge and experience. These included the value of research, clinical perspective concerning research and the CRN role and had been identified from the interview schedule in order to look across the data at these areas. As the data was further analysed main themes, such as leadership and interaction within staff, were identified using an inductive approach. Further sub themes were then identified as they were uncovered (see appendix 22 for a list of codes). Spencer et al (2014) refer to this as moving from an initial process of indexing and sorting to developing categories as analysis and interpretation progresses and it becomes possible to capture the essential meaning of the data and address the central research questions. Therefore across all interviews and focus groups whole group analysis was used. This treats the data produced as a whole without delineating individual contributions so that the group becomes the unit of analysis (Spencer et al 2014). This approach was chosen as the researcher wanted to examine

experiences and perceptions across all the participants. It was expected that these may not be consistent and that although initial themes may match, the further analysis and revealing of sub themes would identify a mixture of findings.

Within this analysis all transcripts and audio recordings were reviewed on several occasions. This allowed the researcher to become familiar with the data and ensure that for the themes that were identified as the analysis progressed, previous transcripts could be re analysed to ensure full inclusion of all data.

4.9.2. Integration of qualitative and quantitative data

The goal of integrating the phase 1 quantitative data and the phase 2 qualitative data is to provide a broad, rich and in-depth understanding of how the CRN workforce is currently organised within acute trusts, the experience of CRNs and the experience and perception of other research staff concerning the CRN workforce within their organisation

Integration is seen as the key to mixed methods research and is defined as the process of linking qualitative and quantitative findings in the course of data analysis (Bryman 2007). Integration can take place at any stage of the research process from formulation of the research question to analysis of the data (O'Cathain et al 2007). As discussed earlier, analysis of both types of data sets involves a process of triangulation. Within this study triangulation was used to examine various aspects of the CRN workforce and experience. The study data was analysed to explore whether findings from the nationwide survey reflected those within the case study where further detail was obtained. Bringing together of the data revealed a greater depth of understanding regarding the issues and experiences of the CRNs and other research staff. Aspects of the CRN experience and overall workforce which were briefly examined from the perspective of the Lead CRN in phase 1 were further explored with the CRNs and other members of the research team in phase 2. Within this the quantitative data was able to highlight the degree of the problem, e.g. is the CRN role misunderstood? The qualitative data was able to further explore this with the

Lead CRNs as well as gaining insight directly from the CRNs. As described by O'Cathain et al (2010) the data can then be explored for convergence, complementarity and discrepancy.

4.10. Ethical considerations

Ethical approval was initially granted by Kings College London University in August 2013 (appendix 14) and amendments following the pilot were approved in August 2014(Appendix 15) (PNM/12/13-123). As no patients were involved in the study approval from the NHS research ethics committee was not required.

The study was classed as "Service Evaluation" according to the definition of the National Research Ethics Service (NPSA -2009). Therefore R&D approval was not required for either phase of the study.

All interviews were recorded and then transcribed. Participants of the focus group were requested not to discuss the items discussed outside of the group. Transcripts were saved on a password protected computer held by the researcher. Locations of the case studies could not be identified on any of the transcripts. Additionally clinical professionals could not be identified within any of the recorded transcripts.

The focus group discussion may potentially affect group participants emotionally due to over disclosure. The researcher therefore, continually monitored how participants felt during the session and included a debriefing session at the end of the discussion which was not recorded. The researcher discussed the topic of sensitive issues and confidentiality at the beginning of each focus group session and reminded participants not to discuss anything outside the group that was discussed during the focus group interview.

4.11. Data Security

All data was handled and managed in compliance with Good Clinical Practice and the Data Protection Act 1998.

All participants were informed that the recordings from the interviews and focus groups would be stored as encrypted files. They were also informed that data would be stored for a period of five years and then destroyed as agreed with Kings College London Ethics Committee. The location of the case study could be identified on the transcripts to ensure anonymity.

4.12. Summary

This chapter has provided an in-depth overview of the study design and methods used within this mixed methods study. The following chapter will present the results of both phases of the study.

Chapter 5: Results

Phase 1 results

5.1. Introduction

This section will present the results from phase 1a of the study. The aim of this phase was twofold:

1) To gain an overview of the current CRN workforce and the teams within which they were based.
2) To identify which organisations had reviewed their CRN workforce and what form this had taken.

Responses given in the analysis are based on the responses to each individual question as different response rates were received for each question. General demographics of the responses will initially be presented. Results will then be presented with respect to each of the six challenges within the 'Organising for Quality' framework.

5.2. Survey population and sample

Phase 1 of data collection involved a national survey of all acute NHS Trusts who were recruiting into NIHR studies as identified within the NIHR recruitment tables 2011/2012 as described in the methodology section. A final total of 173 organisations were identified to be included within the survey. Table 5.2-1 shows the breakdown of trust size defined as either small, medium, large, teaching or specialist.

From a total of 173 organisations, a Lead CRN or someone within the R and D directorate who was responsible for the CRN workforce was identified in 144 organisations (83%). For the remaining 29 (17%) organisations an individual was not identified for the following reasons:

- 1 organisation declined to participate

- 4 organisations did not have a Lead CRN or someone who would be able to complete survey
- 24 organisations did not respond

There were small numbers within each type of organisation where it was not possible to identify an individual except for teaching acute trusts where someone was identified for all 19 of them. The survey was therefore sent to 144 organisations via the online tool survey monkey. A response rate of 77% (111 organisations) was achieved. Figure 5.2-1 illustrates the spread of participants across the UK and shows a good distribution of respondents. Two clusters around London and Manchester are noted where response rates are higher. These may be due to a higher prevalence of teaching and specialist trusts in these areas.

Table 5.2-1 Summary of respondent by Trust type

Type of Trust	Total Number	Total sent survey	Number of replies received
Small Acute	25	21	16 (14.5%)
Medium Acute	46	36	26 (23.5%)
Large Acute	43	38	29 (26%)
Teaching	24	24	19 (17%)
Specialist	19	16	12 (11%)
NHS Scottish Health Boards	14	7	7 (6%)
Wales	1	1	1 (1%)
Northern Ireland	1	1	1 (1%)
TOTALS	**173**	**144**	**111**

Figure 5.2-1 The geographical spread of respondents across the UK. Data are clustered based on the proximity of locations. Generated using mapsdata.co.uk.

5.3. Survey respondents

From the survey responses received, 68% (76/111) were completed by someone in a research nursing related role. The remaining 32% (35/111) were

completed by those in a non-nursing role. Table 5.3-1 shows the role and band of all the respondents.

Table 5.3-1 Distribution of respondents by role

Level of post	Total Number	Post Title	Number of respondents	Total % response per band
Band 6	2	Clinical Research Nurse	1/111 (0.9%)	2%
		Clinical Trials Co-ordinator	1/111 (0.9%)	
Band 7	41	Clinical Research Nurse	26/111 (23.5%)	38.5%
		Trials Practitioner / Co-ordinator	5/111 (4.5%)	
		R&D Manager	6/111 (5.5%)	
		Research Manager	4/111 (3.5%)	
Band 8a	45	Matron	4/111 (3.5%)	42.5%
		Lead CRN	25/111 (22.5%)	
		R&D Manager	10/111 (9%)	
		Research Manager	6/111 (5.5%)	
Band 8b	12	Lead CRN	9/111 (8%)	11.5%
		R&D Manager / Research Manager	2/111 (1.8%)	
		Chief Nurse – R&D	1/111 0.9%	
Band 8c	6	Lead CRN	4/111 (3.5%)	5.5%
		Head of Nursing for Research	1/111 (0.9%)	
		R&D Director	1/111 (0.9%)	

Figures 5.3-1 shows the banding level of respondents per type of organisation. It demonstrates that the larger the organisation so the more senior the level of the individual responsible for the CRN workforce becomes. This is particularly pronounced in the acute teaching trusts, where no respondents were below the band 8 level. This may lead to limitations in the interpretation of the data. However, as this area has not been explored before, it does provide an initial overview which was previously not available.

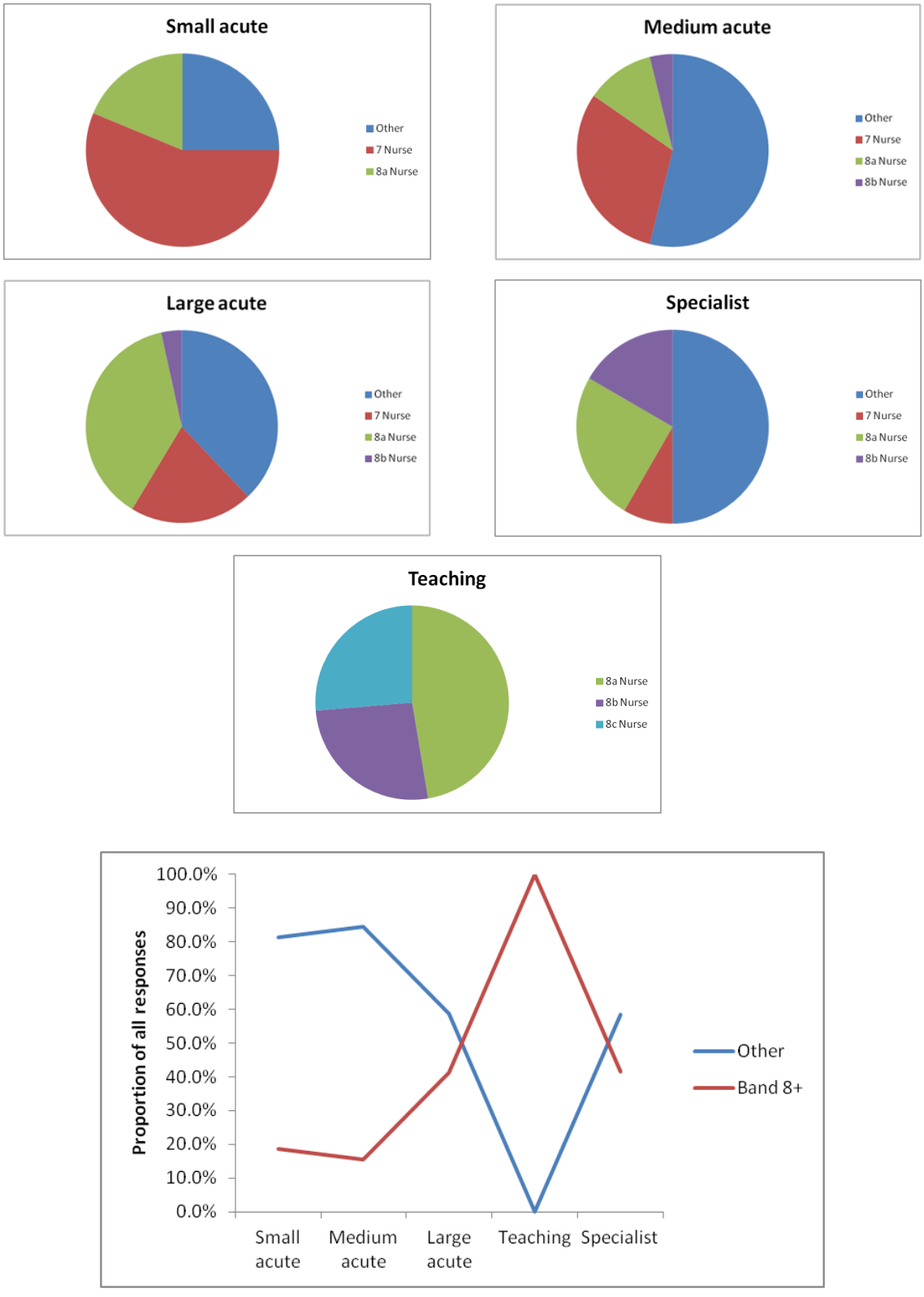


Figure 5.3-1 Questionnaire respondents broken down by banding and organisation type.

5.4. Respondents' employment profile

Respondents were asked to provide information on the length of time they had worked in their current post and their pay band. The length of time that respondents had been in post ranged from newly commenced to 20 years with an overall average of 47 months in post. Sixty-nine percent (74/98) were the first person to hold their role and 21.5% (23/107) had been in post 12 months or less.

5.5. Banding of CRN posts

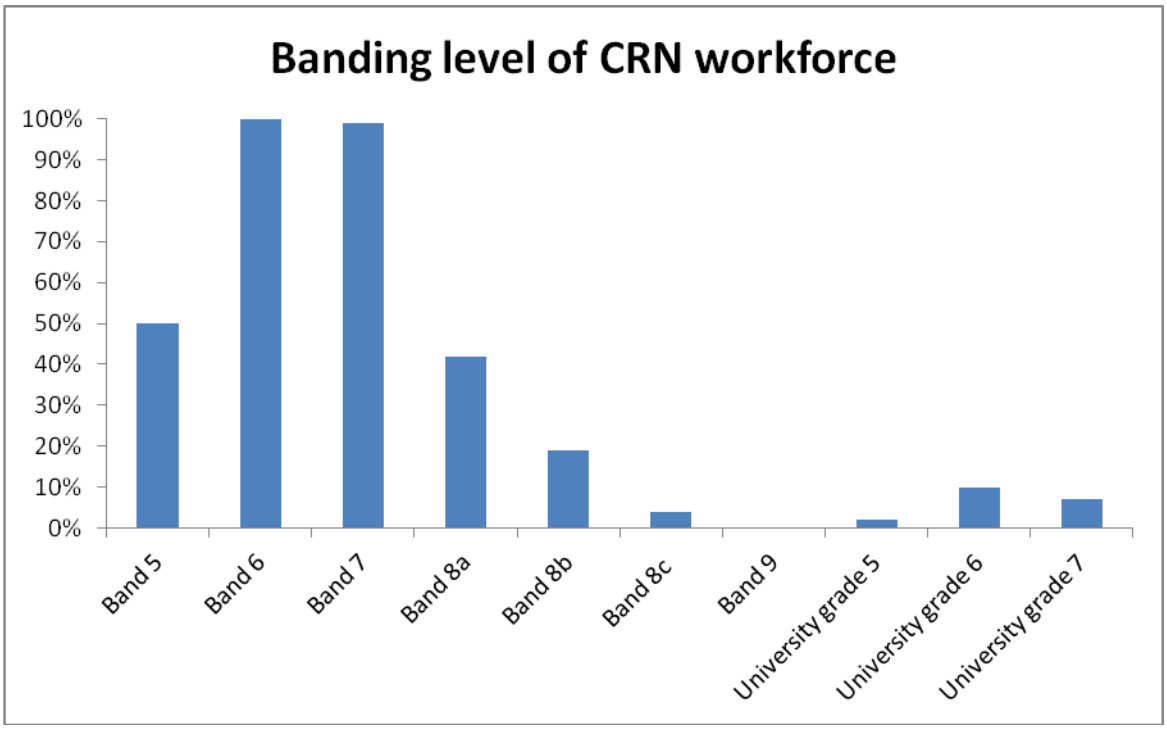


Figure 5.5-1 A graph illustrating the range of pay bands including agenda for change ('Band') and university scales (Grade) for CRNs within all respondent organisations.

The majority of the CRN workforce across all organisations are at a band 6 and band 7 level with only approximately 50% (55/111) having CRNs at a band 5 level. Those who had posts at a band 8 level had small numbers of these posts. Only a very small amount (11/111, 10%) had CRNs appointed through their partner university and those that did were mainly acute teaching trusts (one such organisation was a large acute trust).

5.6. Research areas

The survey asked respondents to indicate the clinical research areas where CRNs were based. As expected, due to the initial set up of the National Cancer Research Networks, the most common clinical area was Oncology. Following this Stroke, Haematology and Cardiovascular research were areas in which significant research was being supported by the CRN workforce. However, within the "other" option respondents also indicated an additional 15 clinical areas where research was running within their organisation, including areas such as ophthalmology, neurology, anaesthetics and occupational health. Figure 5.6-1 shows in more detail the different clinical research areas covered by CRN roles

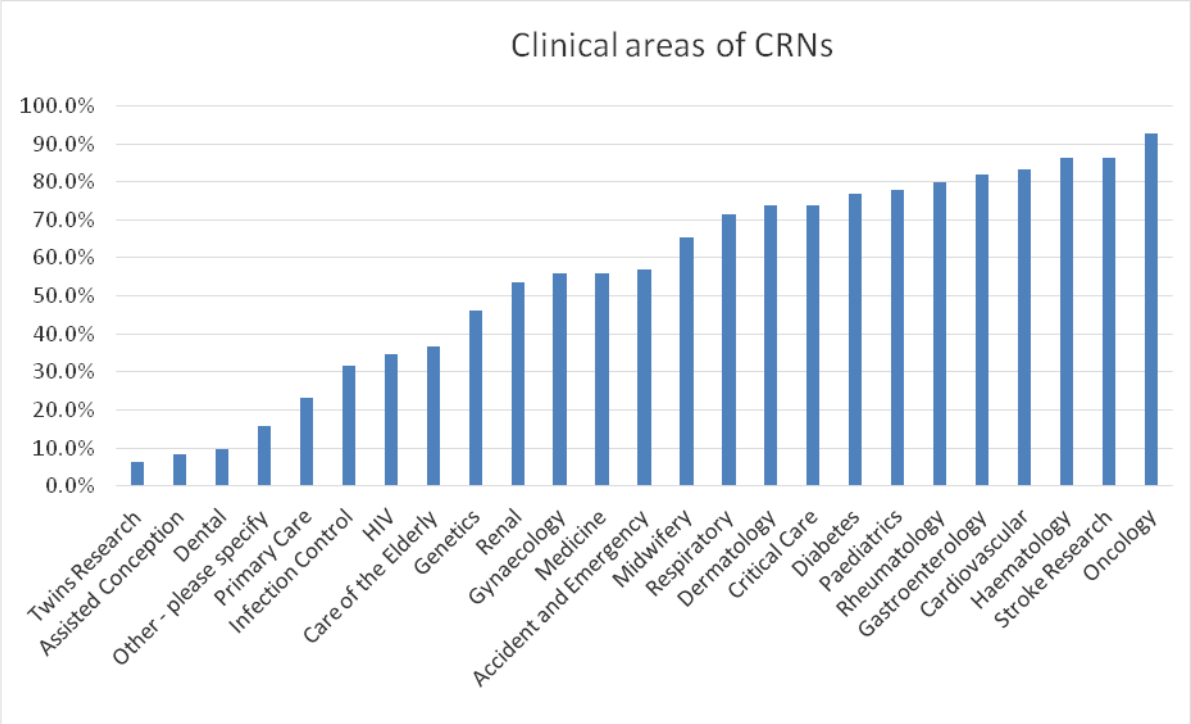


Figure 5.6-1 Clinical areas where CRNs support research studies

Further survey results will now be presented within the six challenges that constitute the “Organising for Quality” framework which was initially described in Chapter 3.

5.7. Challenge 1: Structure

5.7.1. Workforce review

Participants were asked to indicate whether their CRN workforce was reviewed. No time frame was stated within this as due to the recent evolution of the CRN role and the impact of the NIHR on this, it was not expected that organisations would have felt the need to review their workforce over a long period of time. Over half (59/107, 55%) stated that their CRN workforce had been reviewed, 33% (35/107) said it had not and 12% (13/107) were unsure. Actions following the review were as follows:

Table 5.7-1 Actions taken following CRN Workforce reviews

Percentages of 59 organisations reporting having carried out a CRN workforce review	Outcome of review
42.5 % (25/59)	Changes were made within teams but the whole workforce was not restructured.
27% (16/59)	Stated that other changes were made
25.5% (15/59)	CRN workforce was restructured
5% (3/59)	No changes made.

The definition of a workforce review was omitted in the survey as it had not been anticipated - or highlighted in the piloting of the survey - that clarification would be required. Responses from the open comments indicated that interpretations to this ranged from carrying out a full review to a review of just individual teams or roles. The open comments (n = 53), were coded to gain further detail on the other actions taken and the most common was that an internal restructure of teams and / or posts had been carried out – 34% (18/53). Only 13% (7/53) respondents were currently reviewing their workforce and 9.5% (5/53) had established a more generic workforce to provide greater cover for studies.

Table 5.7-2 looks at type of organisation and whether it has been reviewed or not. The data was examined in order to determine whether any relationship existed between organisation type and review. As shown below a greater number of larger organisations (incorporating large, specialist and teaching) had reviewed their workforce compared to those of the same type that had not. However, there was no statistical significant difference between the two proportions ($x^2 = 0.609$, xd.f, $p = 0.44$).

Table 5.7-2 Examining the relationship between Trust type and review status.

Trust type	Organisations which have reviewed	Organisations which have not reviewed
Small & Medium	34% (20)	40.5% (21)
Large, Specialist & Teaching	59.5% (35)	50% (26)
Scotland/other	6.5% (4)	9.5% (5)

5.7.2. Research structure

A majority (81%, 71/88) of respondents stated that their CRN workforce was embedded within a "defined research structure". Further clarification was gained and respondents were also asked to indicate from a list what structure applied to their workforce. The results were as shown in Table 5.7-3

Table 5.7-3 Is your CRN workforce embedded in a defined workforce structure?

Answer Options	Response Percent (Count)
RN workforce works as part of the Local Research Networks or within one of the divisions.	86% (73)
Organisation has one or more Clinical Research Facilities (CRFs)	34% (29)
Organisation is part of the Network of Experimental Cancer Medicine Centres (ECMC)	16.5% (14)
Organisation has been assigned as one of the NIHR Biomedical Research Units	10.5% (9)
Organisation is part of an Allied Health Sciences Centre	10.5% (9)
Organisation has been assigned as one of the NIHR Biomedical Research Centres	9.5% (8)
Answered question (Skipped question)	**85 (26)**

The majority of respondents (86%, 73/85) stated that their workforce was part of a Local Research Network. As the NIHR supports research within the NHS this is only relevant to organisations within England. For the respondents located in Scotland, Wales and Northern Ireland, not all aspects of this question were relevant (although Clinical Research Facilities are not unique to the NHS so this aspect was relevant to all). Some respondents stated that their CRNs were employed directly by the trust and did not give further details. Many had a mixed model in place and were planning to formalise this in the future.

There was also a diversity of responses in relation to team structures within the CRN workforce (table 5.7.3).

Table 5.7-4 CRN team structures

Answer Options	**Proportion of response (count)**
Working directly with Consultants on their research studies	63.5% (52)
In a structured research team within one clinical area	55% (45)
Working within clinical teams with non-research colleagues	51% (42)
Working within a Clinical Research Facility	40% (33)
Working in one area in different research teams	38% (31)
Working independently in one or more clinical teams but not within a research or clinical team	21% (17)
Other (please specify)	30.5% (25)
Answered question *(skipped)*	**82 *(29)***

Open comments in response to this question enabled respondents to indicate that their CRNs worked within a “generic” team and covered areas depending on where studies were running. Although the survey did not specifically ask questions regarding a generic workforce structure, those who indicated this as their structure were more likely to be based within a small or medium acute trust and have a smaller CRN workforce size (20 CRNs).

5.7.3. Research roles within teams

The survey listed 12 potential research roles (clinical and non-clinical) and asked respondents to indicate which ones were employed within their organisation as shown in Figure 5.7-1 below.

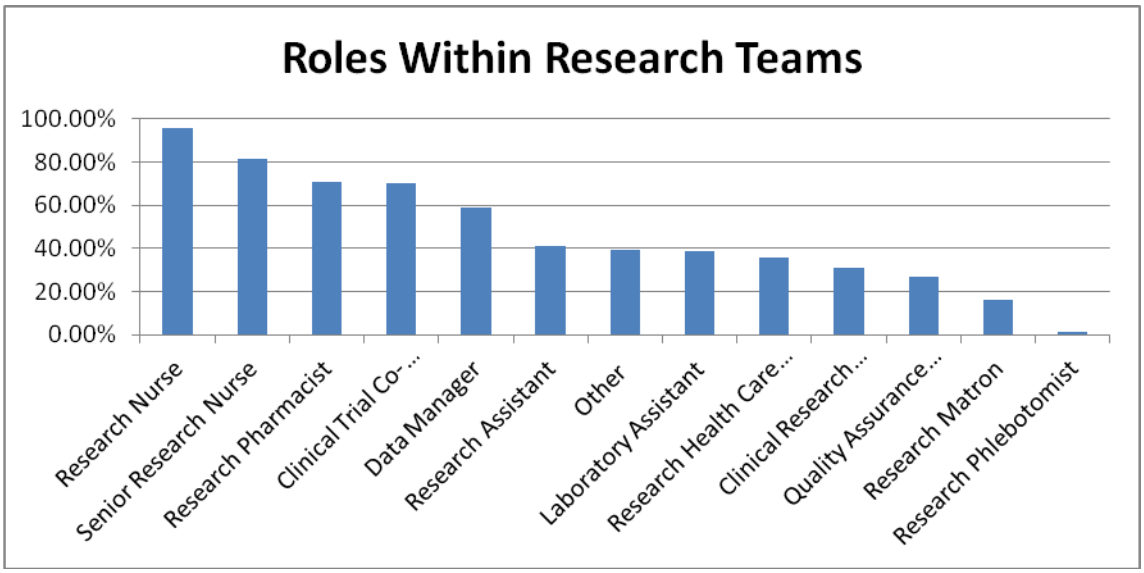


Figure 5.7-1 Range of roles within research teams. The graph shows the proportion of total respondents who identified the named role within their organisation

Within the “other” category a further 29 roles were provided with some relating to other members of the multi-disciplinary team (e.g. Research Radiographer, Research Dietician and Research Pharmacy Technician). Many of these roles appeared to be non-clinical (e.g. Research Co-ordinator, Research Administrator, Research Practitioner and Research Officer). No further information was given regarding the remit and responsibilities of these roles which may overlap in their day to day activities. The wide range of roles and job titles identified in the survey demonstrates the current lack of consistency across organisations with regard to research activity. Many non-clinical roles have been developed in response to a growing research portfolio, increased funding and a recognition of the value and need for such roles within a research team. This finding will be revisited further in the discussion chapter.

Figure 5.7-2 shows the ways in which CRNs are appointed into the organisation. A significant percentage (81%, 73/90) was appointed through the

Research & Development (R&D) department (perhaps unsurprisingly as organisations receive research funding from the NIHR and this is managed through such departments). Respondents also indicated other routes through which CRNs were appointed such as via the CRF, which would then come under the R&D department, directly by the trust or via another trust through a local NIHR research network.

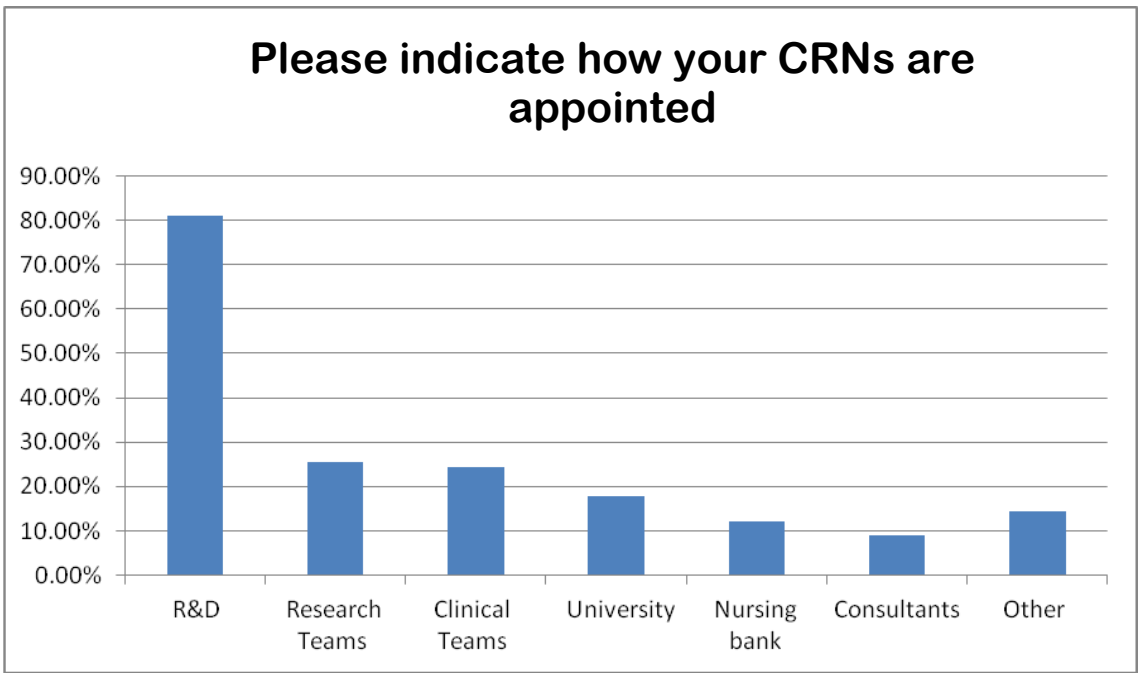


Figure 5.7-2 Routes by which CRNs were appointed into the organisation

Table 5.7-5 shows the funding sources for the CRN workforce. The majority of respondents indicated that their main source of CRN funding was from the NIHR (as this only covers England those that did not select this option were based within one of the other UK countries). Funding from Pharmaceutical Companies formed the second main source of funding indicating that many CRNs also work on a commercial portfolio of clinical trials. Most organisations listed other funding sources. Small and medium acute trusts were more likely to employ their CRNs solely via the R&D department alone (especially when they had a relatively small workforce). Those organisations with a large workforce were more likely to employ their CRNs through several routes including R&D, reflecting the various funding streams that support the CRN workforce.

Table 5.7-5 Sources of funding for CRN posts in respondent organisations.

Answer Options	Response Percent (Count)
NIHR funded	96.6% (85)
Pharmaceutical Company	59.1% (52)
Research grant - e.g. - MRC	42% (37)
Charity grant - e.g. - CRUK	33% (12)
Nursing Directorate	13.6% (29)
Other (please specify)	24% (21)
Answered question (skipped)	**88 *(23)***

5.7.4. Line management

Figure 5.7-3 illustrates the role of those responsible for the line management of CRNs. The majority of organisations (82%, 73/89) have senior CRNs responsible for the line management of some CRNs within their workforce. However, 36% (32/89) indicated that CRNs were line managed by a clinical nurse (Matron, Consultant nurse or CNS) and 38% indicated that they could be line managed by the R&D Manager. Other post holders had line management responsibilities in a small amount of organisations including Consultants (16%, 14/89) and Research Managers (16%, 14/89). In 10% (9/89) of responses there was no nursing involvement in the management of the CRN workforce. Overall, the table demonstrates that there is often a range of managers, nursing and non-nursing, involved in the line management of the CRN workforce.

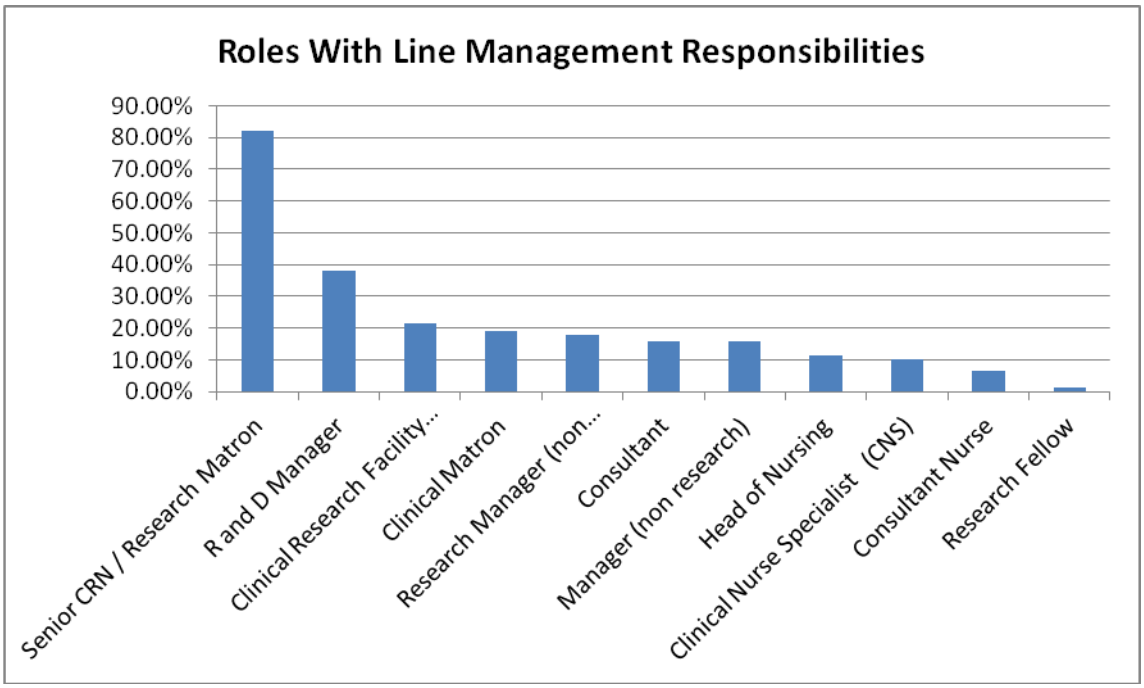


Figure 5.7-3 Line management of CRNs. The proportion of respondent organisations indicating named post holders are responsible for CRNs. Question: "Please indicate which of the following in your organisation are responsible for the line management of CRNs - tick any that apply."

5.7.5. Summary

In relation to the 'structural' challenge, the survey identified that just over half of the organisations had reviewed their CRN workforce but only a few of these (25%, 15/59) had carried out a full review. The majority of respondents indicated that a review would usually take the form of an internal re structure of teams and / or posts. The survey also identified the lack of consistency both within and across organisations as to the structure of the CRN workforce and the establishment of teams within organisations, especially relating to the range of possible research related roles within teams, sources of funding and line management of post holders.

5.8. Challenge 2: Culture

The questions within this section aimed to examine and reveal how research is viewed across organisations and what value and importance is placed upon it. They also aimed to explore the understanding from clinical staff of the CRN role and examine how CRNs were perceived whilst in the clinical environment.

Respondents were asked to rate the importance of research across their organisation on a five point Likert scale. The majority of the participants (70%, 72/102) agreed or strongly agreed that research was considered important or relevant within their organisation and 51.5% (52/102) agreed or strongly agreed that research was considered important by senior nurses across their organisation. However, only 26.5% (27/102) agreed or strongly agreed that research is considered important by all staff within the clinical areas. This was reflected in the open comments of all the respondents who acknowledged the strategic importance of research. For example, respondents commented that the “CEO and clinical leads think it is important to raise the profile” and that “staff will tell you that research is important to the organisation”. Therefore for some respondents there was a feeling that “clinical research is definitely rising up the priority list” and that they were “moving forward in many areas”.

For many organisations there was recognition from the Executive team of the importance of research - it was “mentioned in most strategy documents” and often seen as “useful and important” - but respondents also highlighted the difficulties from an operational perspective. Many comments focused around the lack of priority accorded to research and variation in response across their organisation. Respondents felt that research was “viewed as an added extra” and “not fully embraced as core business”; there was an overall “lack of understanding“ and “clinical areas still struggle with seeing research as important”. Respondents highlighted a feeling of “apathy” from staff due to “added pressures” from a busy clinical workload and that research was a “nice to have not an important to have”.

There was a feeling of a lack of consistency within organisations as to the importance of research. Respondents commented that the response was “highly variable” with “pockets of excellence but still a long way to being core business”. One respondent commented that “in some areas it is seen as core business but in other areas research is seen as unimportant” while another stated that “nurses on the wards where research protocols take place are very helpful but the senior nurses across the trust are not so engaging”.

Some of the issues around the importance of research seem related to it being seen as separate from clinical care. CRNs have been viewed as a “university employee” and “one of the historic barriers was probably the fact that research was very much seen as the domain of the university and not the trust”. Although the development of research units known as Clinical Research Facilities (CRFs) has provided dedicated space for research , it has also led to it being seen as a “separate entity” with “limited understanding of the day to day running of the unit” and a lack of “visibility”.

Responses relating to the understanding around research 57% (56/98) disagreed or strongly disagreed that research was misunderstood and there was little general support for its success. However, 69.5% (67/97) did agree or strongly agree that research is generally low on people’s agenda due to the importance given to and workload implications from government targets, initiatives and reports. Respondents felt that “there is a general positive attitude to research” and “staff are aware of its importance and in calm periods are keen and happy to facilitate”. For many clinical workload was a big factor and “when the pressure is on one of the first things to suffer is research”. There were many reasons stated for this including that “clinical requirements always take priority”, “research is low on peoples agenda because of competing pressures” and “ research can often be deemed as an add on”. However, research teams are keen to increase awareness of research. One respondent explained that the CRNs “are working hard to improve this (research awareness and understanding) overall and beginning to see results where research is seen as a natural treatment choice and not as an optional extra”.

The survey also looked at the understanding of the CRN role. Forty per cent of respondents (39/98) said that the role was not understood and 32.5% (32/98) were not sure. Only 27.5% (27/98) felt that the CRN role was understood. Respondents felt that clinical nurses “very often lack insight into the true nature of the role”, “fail to see the research nurse role as a clinical role” and “senior nurses often ask how are research nurses going to get revalidated as they need to demonstrate clinical practice”. Respondents explained that often there is a lack of understanding as to what the role involves with clinical nurses thinking it is an “easy option”, “a computer based job” and would “openly admit a lack of knowledge and confidence in managing research nurses”. Respondents also felt that clinical nurses “do not understand the varied aspects of the role”, “the scope of the role” and that generally research “is an add on rather than integral to the day to day work of the clinical area”. Reasons for the lack of understanding included that it is “difficult to see what the role involves without spending some time in research” and “there is confusion regarding the role of the research nurse and the nurse researcher”. Some even felt that CRNs are “often viewed with suspicion when in outpatient clinics or ward areas until the role is explained and the staff realise that they do not have to do the work”.

Some respondents did comment in a more positive way and highlighted some of the work that had been done to “dispel the myths”. They felt that some nurses “partially understand our role” and that this is better “in areas where there is a strong research culture” but it depends on “how much we have infiltrated the area”. Lead CRNs had spent time working to increase awareness of the role. One commented that they now “hold regular research forums and participate in events in wards and across the organisation”. This meant that now awareness was “improving slowly but surely” and there had been “huge improvements” so that “many more colleagues have a greater understanding of the research nurse role now compared to 5 years ago”.

Despite an apparent lack of understanding and awareness of research and the CRN role, 92% (95/103) of respondents felt that non research colleagues did help to facilitate research. Related to this 92% (84/91) said that staff would inform CRNs about patients who may be suitable to be included in studies and

76% (69/90) thought that clinical staff are interested in the studies and willing to remain updated about new protocols. Furthermore, 83% (74/89) thought that staff are willing to collect a small amount of research data if seeing the patient as part of a clinical appointment (See Table 5.11-1).

Despite this apparent support, the majority of comments related to this indicated that within most organisations there was a “mixed” and “patchy” response to research with “varying degrees of engagement”. Reasons for this were related to “how common research activity is and the relationships with the research team”. Many of the comments indicated that the reason for the difficulties experienced in gaining engagement and support were due to the fact that “research is not embedded into normal practice and care”. Respondents also indicated that clinical areas often felt that research “adds to their clinical workload which is already huge” and “they feel it is not their remit to contribute even if it is something that is routinely done for their patients”. Respondents also indicated that clinical staff often view research as separate with one commenting that “there is a reluctance to collect any data which is additional to routine clinical care as nurses do not see this as part of their role and perceive requests for help as detracting from routine patient care”. One Lead CRN summed it up as follows:

> *“I could answer yes or no to all of the above questions as there are some engaged staff who will do all these things and some who absolutely would not. We experience extremes of negativity and positivity and everything in between”*
>
> — **Question 11, comment 40**

Many of the respondents indicated that they and their team spent time and energy in working to raise the awareness of research in order to gain support from clinical colleagues. This included assisting CRNs to “maintain good links with clinical and non-clinical staff”, “build up very good relationships within their immediate clinical teams so the awareness of local specific research is relatively good” and develop “strong working relationship with wider clinical teams as this is key to continuity, consistency and quality of care for patients”.

Only 44% (43/98) respondents agreed or strongly agreed that CRNs feel welcome within the clinical environment and are allocated dedicated space to see research patients; 28.5% (28/98) disagreed or strongly disagreed with this and 27.5% (27/98) were unsure or neutral in their response. Related to this 52% (51/98) agreed or strongly agreed that the CRNs frequently comment on the difficulty of seeing patients in the clinical environment and being able to spend the required amount of time with the patient; 30.5% (30/98) disagreed or strongly disagreed and 17.5% (17/98) were neutral or unsure (see Table 5.10-1).

Respondents indicated that CRNs experience a range of responses across their organisation when seeing patients for their research appointments within the clinical area. Responses experienced were “variable”, at times “obstructive” but often “dependent on department”. Respondents indicated that often the “CRNs feel welcome but due to capacity issues they cannot often find space” and that often there are “challenges in many areas to find dedicated space due to clinical pressures and patient flow”. One respondent said that “clinical staff help as far as possible to enable rooms to be available for study visits, but if the rooms are required for clinical visits then study visits are cancelled”. Others referred to “borrowed space” or “a lot of variety across the trust in the physical resources available to the research teams”. So that overall many agreed that some of the problem lies in the fact that “the CRN is at the bottom of the chain when trying to organise space”. This may account for why 59% (57/98) of respondents indicated that CRNs report that patients are sometimes missed, due to the difficulty in organising allocated space.

Therefore, in summary research is not yet viewed as core business or integrated into clinical care. Clinical staff do acknowledge it is important and from a strategy perspective it is viewed as important and relevant. However, as it is not yet seen as a priority there is a lack of consistency in staff engagement and as clinical workload increases the importance assigned to research drops as staff focus on competing pressures such as “acuity of patients, safe staffing and meeting quality targets and KPI’s (key performance indicators)”. There is a similar picture with the CRN role as it is seen as not understood, not a clinical

role and a lack of understanding regarding the workload. At times it is also confused with the role of a Nurse Researcher. Many CRNs and their teams have worked hard to increase the awareness and understanding but there is a recognition that this work will need to be ongoing.

5.9. Challenge 3: Education

The education of the CRN workforce was examined in order to gain an overview of how CRNs are supported both academically and in wider personal development terms. The survey aimed to explore both induction programmes at commencement of the role and ongoing training to support professional development. Related to this was questions concerning funding support and time allowed in which to attend training courses. The current academic profile of the CRN workforce was also explored.

Looking at the education of nurses, 90% (93/103) of respondents said that their organisation supported the professional development of nurses. Positive influences included that “R & D hold funding for the research team and do not put up any barriers to study days” and “nurses are encouraged to keep learning and progress”. Respondents also commented that “research nurses are very fortunate as we get quite a lot of opportunities compared to the general ward staff” and “we are always actively supporting development opportunities supporting CRNs through leadership courses as well as Masters Programmes”. Respondents also remarked that their nurses had been “successful with NIHR fellowships”.

However, within this many constraints were also mentioned such as “funding resources are limited and there are significant challenges in releasing staff from clinical duties” and it “has to be mandatory for the job role”. One respondent felt that “the organisation appears supportive but opportunities appear limited” and another stated that “despite claims that it does there has been little evidence of this”. For one respondent CRNs were not a priority when allocated courses and

“only tend to get on courses like nurse prescribing when there are places left after the clinical staff have been offered it”. This was confirmed by another who stated “other CNSs do get professional development but research nurses do not have that support”. One respondent summarised their situation as follows:

> *“staff can access training but have to complete in their own time. Generally speaking there is support in principle but things are tight so due to workload and recruitment and retention issues that this makes it very difficult”.*
>
> — **Question 14, comment 24**

The survey aimed to examine the academic profile of the CRN workforce. However, the results demonstrate that many respondents were unsure of this and a large amount indicated that they did have CRNs at some or all of the level options but were not sure of numbers. Many respondents confirmed their CRNs had a first degree but of those who responded, 55% (37/67) did not know the exact numbers. This was the same for the Masters and PhD / Doctorate programmes although the numbers stated were smaller. This question also received the smallest number of responses which may indicate that respondents did not have this information regarding their workforce. Those with a larger workforce were less likely to provide this information, possibly demonstrating the difficulty in obtaining it and keeping it up to date for large numbers of staff.

As shown in Figure 5.9-1, funding for academic programmes appears to be limited with less than half of respondents (ranging from 22-49%) confirming that CRNs were always able to access financial support from a variety of sources. Approximately a third of respondents (ranging from 28-38%) confirmed that funding would occasionally be available. Internal funding related to the CRNs own department was the most common source of funding although all possible options within the survey were confirmed as available.

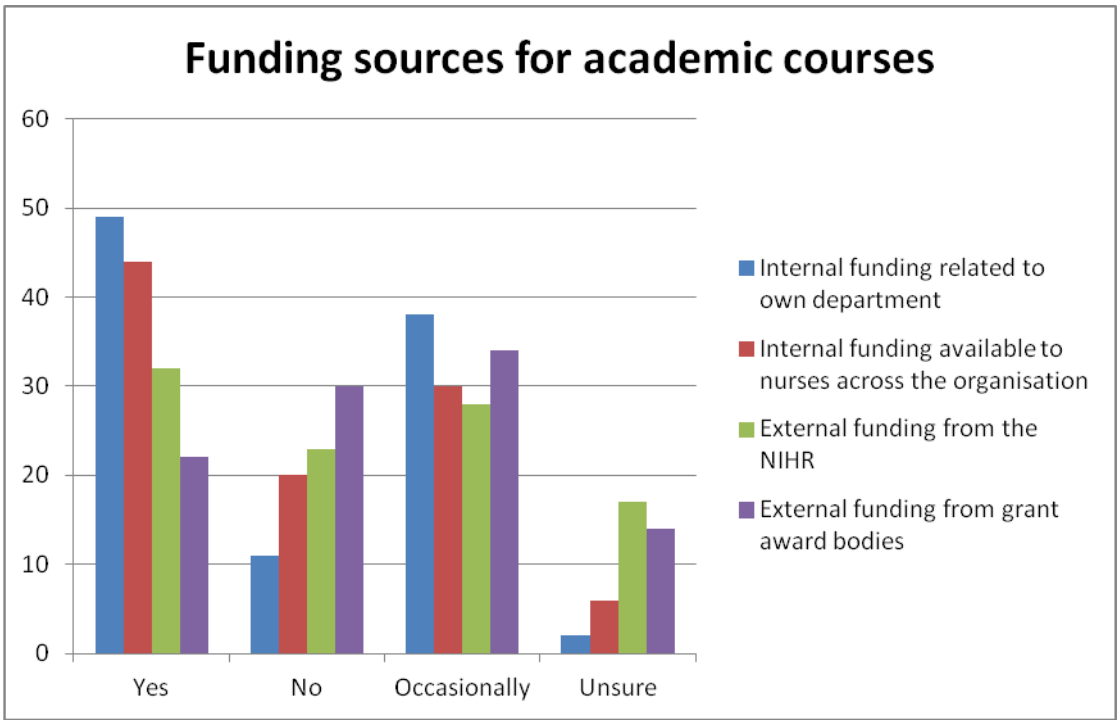


Figure 5.9-1 Source of funding for academic courses.

There was a range of responses as to how the study leave was arranged within organisations. Some indicated it was “negotiable on a case by case basis”, “at Managers discretion” or “according to trust policy”. Others indicated it was “related to the organisational training needs analysis linked with the appraisal” or “considered in relation to how relevant the course is to the role”. One organisation allowed 18 days a year for study leave but this was an exception.

Respondents indicated which induction programmes their CRNs attended when initially commencing their role. As shown in table 5.9-2, 96.5% (87/90) indicated their staff attended a Corporate Trust induction programme, 96.5% (78/81) indicated their staff attended a local induction programme and 91% (79/87) a research induction programme.

Slightly fewer (82%, 54/66) attended a trust nursing induction programme. A few respondents (33.5%, 4/12) indicated their CRNs attended other induction programmes although no examples were given.

Table 5.9-1 Summary of induction programmes for new research nurses in respondent organisations.

Answer Options	Yes	No	Response Count
Corporate Trust Induction	87	3	90
Trust Nursing induction	54	12	66
Local Induction programme	78	3	81
Research Induction programme	79	8	87
Other	4	8	12
Other (please specify)			15

CRNs also attended a range of generic and research-related training as indicated in Figure 5.9-2 and Figure 5.9-3 respectively.

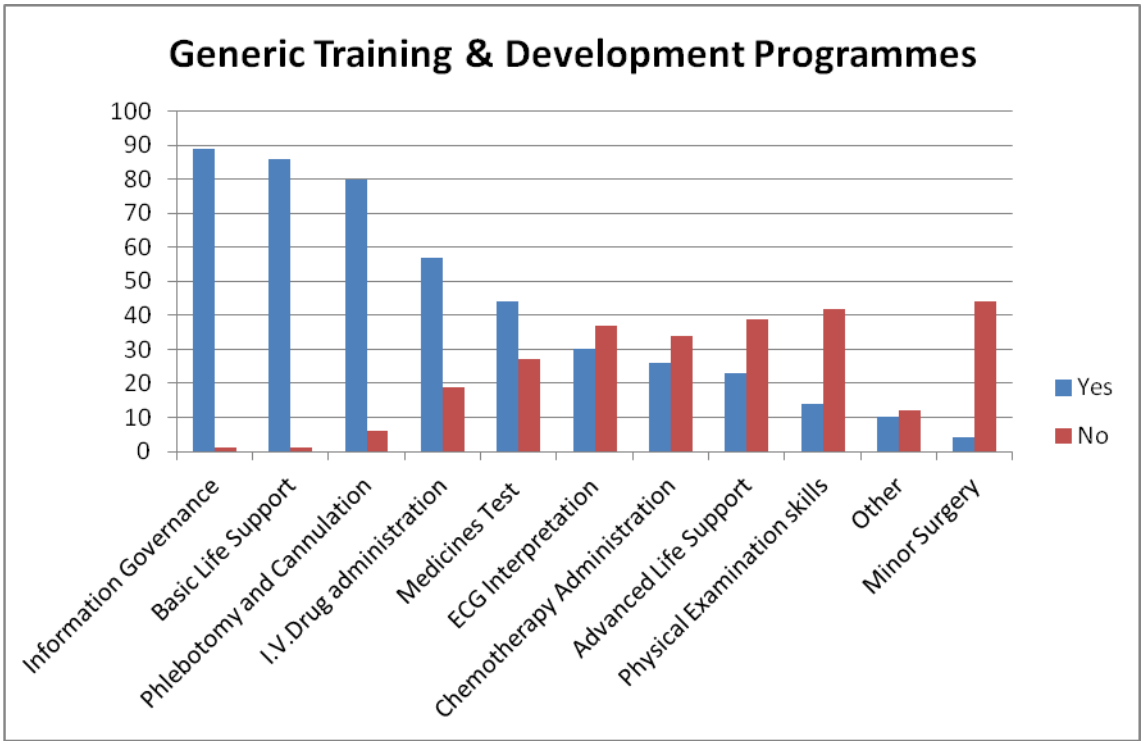


Figure 5.9-2 Non research-specific training & development courses available for CRNs. Question: "Please indicate which generic Training and Development programmes a RN within your organisation is expected to attend - Tick any that apply" (indicates number of respondents out of 90)

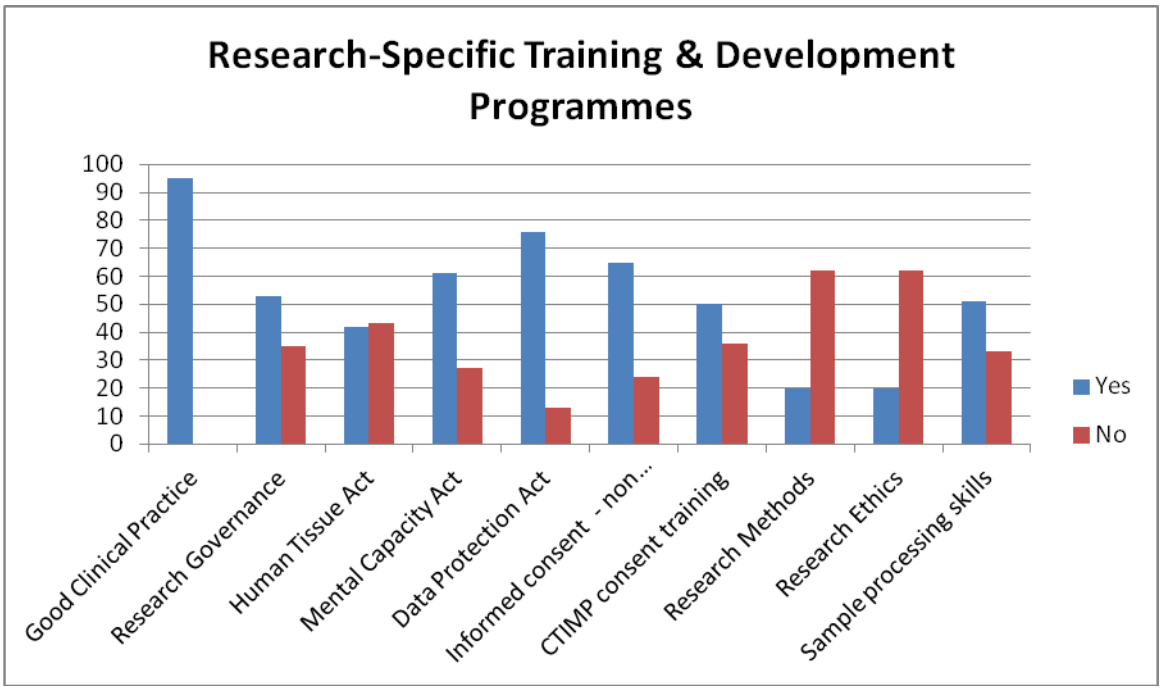


Figure 5.9-3 Research-specific training & development courses available for CRNs. Question: "Please indicate which research training and development programmes a CRN within your organisation is expected to attend?" (Indicates number of respondents out of 95).

Within the required clinical skills, additional training included anaphylaxis, physical assessment skills and nurse prescribing. For research related training, additional requirements were dependent on the individual's role and CRNs were "expected to attend any course relevant to the studies that they do". This included skin biopsy training and handling of dry ice training.

All respondents confirmed that their CRNs undertook regular Good Clinical Practice (GCP) training. However, although the Human Tissue Act (HTA) covers the removal of human tissue including blood and 93% respondents confirmed their CRNs undertook phlebotomy training, only 49.5 % confirmed that their CRNs received HTA training. The survey did not question rationale for answers although organisations may provide informal practical training which respondents may not have included within their responses.

A small number of respondents confirmed that they ran a regular structured training programme for their CRN workforce (26.5%, 24/91). The frequency of these programmes varied within and across organisations ranging from monthly to annually. For those who ran a regular session the duration was generally one

to two hours but respondents indicated that their annual training sessions generally ran for a whole day. Some organisations incorporated their mandatory research training sessions within their programme (examples included GCP, consent and data management). Others included “mixed generic sessions related to research and general nursing updates” within their programmes. Respondents generally indicated that these sessions were not for those working in a non-research related role with all respondents except one confirming that the sessions were open to anyone working within research (including R&D Managers).

In summary, the majority of respondents reported that their organisation supported the professional development of nurses. However, within this there was a mixed response with some reporting that CRNs are more fortunate compared to clinical staff while others felt that CRNs were not a priority. Within the CRN role there was a range of courses attended by CRNs both at induction and within the role to support professional development. Challenges to support training include funding and time allowance and there was a range of developmental opportunities across organisations. Although academic development was supported the majority of respondents were unable to describe the academic profile of their workforce. This was especially on those organisations with a large CRN workforce.

5.10. Challenge 4: Politics

Survey questions related to the ‘political’ challenge aimed to explore the reception that CRNs receive within the clinical environment and how accommodating clinical staff were towards them, including whether staff would help with identifying dedicated space for CRNs or support small amounts of workload related to research (such as helping to identify suitable patients). The role of CRNs within the research team and degree of Principal Investigator (PI) involvement was also explored.

Table 5.10-1 Summary of responses relating to the Political challenge

Answer Options	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure	Response Count
RNs are made to feel accepted within the clinical environment by their nursing colleagues and efforts are made to accommodate their requirements.	7% (6)	57% (50)	20.5% (18)	12.5% (11)	1% (1)	2% (2)	88
Clinical nurses are happy to help identify suitable patients for studies if asked or collect small amounts of data if requested.	4.5 % (4)	51% (45)	29% (26)	12.5% (11)	1% (1)	2% (2)	89
The RNs find the clinical environment a difficult working environment.	2% (2)	27.5% (24)	28.5% (25)	33% (29)	8% (7)	1% (1)	88
The RNs within the team are able to express their own ideas and opinions in tem meetings and have an influence on decisions being made.	34.5% (31)	52.5% (47)	12% (11)	0	0	1% (1)	90
The research team (PIs and RNs) meet regularly at a dedicated research meeting and individual PIs discuss the studies they would like to set up taking into account the current capacity of the research nurse workload.	18% (16)	50% (45)	19% (17)	10% (9)	2% (2)	1% (1)	90
My staff turnover is no different compared to the general nurse workforce in my organisation.	10% (9)	36% (32)	11% (10)	25% (22)	14.5 % (13)	3.5 % (3)	89
The PIs are actively involved in all stages of their research projects and regularly check on its overall progress and the progress of the patients involved.	11%(10)	42% (37)	31.5% (28)	13.5% (12)	2% (2)	0	89
The PIs regularly engage with the progress but leave the RNs to take overall management of their project.	27.5% (24)	53.5% (47)	12.5% (11)	4.5% (4)	2% (2)	0	88
It can be difficult to involve the PIs in the day to day leadership of their projects.	11% (10)	39.5% (35)	27% (24)	16% (14)	5.5% (5)	1% (1)	89

Table 5.10-1 shows the reception experienced by CRNs in the clinical environment and that 63.5% (56/88) agreed or strongly agreed that CRNs are made to feel accepted within the clinical environment by their nursing colleagues and efforts made to accommodate their requirements. 55% (49/89) also agreed or strongly agreed that the clinical nurses are happy to identify suitable patients if asked, or collect a small amount of data if requested. Only 29.5% (26/88) respondents felt that the CRNs find the clinical environment a difficult working environment.

Many of the free text comments provided demonstrated that overall the response experienced by CRNs in the clinical environment can be very varied and inconsistent across an organisation. Some respondents felt this question was “difficult to answer as some areas can be very involved and happy to contribute to the research but others can be quite difficult to build up relationships with” whilst others said it was “difficult to give a blanket answer for the whole workforce as it depends on the area they work”. Some referred to a “struggle” and “feeling daunted” when in the clinical environment. However, respondents did comment that “staff are accommodating and generally supportive” and that “there is a willingness of the clinical staff if approached”. There was a wide agreement that clinical space is a difficult and frequent issue with one respondent remarking that “lack of space is the main issue why research nurses find it difficult to fit into the clinical environment and be accepted”. Others commented that “space is often an issue particularly in the acute areas where CRNs are ideally allocated space within the department but research is not seen as important enough to warrant this”. The impact of this can be that CRNs “feel they are getting in the way of the clinical nurses” and that they may be “moved from room to room depending on the number of medical staff requiring rooms”, so that at times “there is nowhere for the CRNs to see patients which means they have to waste time looking for a suitable area”.

There was a strong response that the CRNs are involved within their research team with 86.5% (78/90) agreeing or strongly agreeing that CRNs within the team are able to express their own ideas and opinions in team meetings and

have an influence on decisions being made. A majority (68%, 61/90) agreed or strongly agreed that the research team (PI's and CRNs) meet regularly at a dedicated research meeting and individual PIs discuss the studies they would like to set up taking into account the current capacity of the research nurse workload. Again free text comments indicated a varied and inconsistent experience across different teams with one commenting:

> *"answers vary considerably between teams. Some have a dedicated nurse team and monthly meetings to approve study set up/acceptance onto the portfolio. Other research nurses work alone or with a colleague in other specialities across the trust. Nurses employed through the university work exclusively with a team and I do not know how a decision is made" – Participant x*
>
> — **Question 51, comment 3**

Some felt that the CRNs "are able to express ideas and opinions but not necessarily always able to influence" and that there is a "variation in team discussions and agreement on capacity depending on the size of the research team".

Exploring Principal Investigator (P.I) engagement, 53% (47/89) agreed or strongly agreed that the P.I's are actively involved in all stages of their research projects and regularly check on its overall progress and the progress of patients involved. However, 81% (71/88) agreed or strongly agreed that the P.I's regularly engage with the progress but leave the CRNs to take overall management of their project and 50.5% (45/89) agree or strongly agree that it can be difficult to involve the P.I's in the day to day leadership of the project. The free text comments highlighted the varied engagement of P.I involvement in the studies. Respondents referred to "some who are very active and very engaged" whereas others "need constant encouragement from the research nurses to engage". One respondent commented:

> *"P.I role is variable. There are some who are extremely engaged and demonstrate active P.I oversight, whilst others it is more challenging for the CRN to engage with them"*
>
> — **– Question 49, comment 38**

Looking at staff turnover, 46% (41/89) agreed or strongly agreed that theirs was no different compared to the general workforce in their organisation. Free text comments related to this reflected the same breakdown as the Likert scale scoring. There was an approximate equal amount of comments related to whether respondents felt they had a high or low turnover rate. Those who felt it was high related this to "CRNs being on short term contracts which are a difficulty that other clinical areas do not have". One of the respondents summed up many of the comments with the following:

> *"Funding for the nurses via the NIHR is on an annual basis. This does not provide stability for the nurses who have families and mortgages to pay and prefer to have a permanent contract. A lot of time and effort is spent in training research staff and then they leave for permanent posts".*
>
> — **Question 51, comment 18**

Some felt their "turnover is probably lower than the rest of the organisation". For most this was probably a subjective opinion as it was not formally measured. Respondents equated this to "the team being dynamic and friendly" and that "the majority of nurses wish to remain and pursue research as a career option".

Almost half (45%, 43/95) respondents said that their CRNs worked across more than one organisation. In terms of organisation of governance requirements (honorary contracts / research passports), of these 67.5% (29/43) said it was a very easy and smooth process, 23% (10/43) said the process was not so easy and seemed to take longer than necessary and 9.5% (4/43) said the process was very difficult and slow which lead to delays in the study. There was a limited number of free text comments to this question and as only 39% (43/111) of the total survey respondents answered yes to this question, indicating that

their staff worked across more than one organisation, this does not seem to be a significant issue that Lead CRNs deal with.

Therefore, in summary over half the respondents said that CRNs feel accepted within the clinical environment. However, the reality within organisations was that the response was varied and inconsistent. The main difficulty appears to be the availability of dedicated space for CRNs to see their research patients. The role and influence of CRNs within the research team appears variable. Respondents indicated that CRNs often take overall management of the research studies with some indicating the difficulty in ensuring P.I engagement. A main influence on staff turnover within the CRN workforce appears to be their contract of employment which for some is renewed annually and so provides less security.

5.11. Challenge 5: Emotions

Questions relating to the emotional challenge aimed to explore the awareness had by clinical staff to research and the CRN workforce. This section also looked at adherence to research governance requirements and whether the CRNs experienced any difficulty in achieving compliance with the research team.

Table 5.11-1 Responses related to research awareness within respondent organisations

Answer options	Very aware	Somewhat aware	Neutral	Not v. aware	Unsure
The presence of a dedicated nurse workforce related to research	22.5% (22)	60% (59)	5% (5)	12.5 % (12)	0
The importance of research to the national NHS agenda	15% (15)	43% (43)	21.5% (21)	18.5% (19)	0
The current structure of research within your organisation and the way to access resources to support research studies they may wish to run	11.5% (11)	43.5% (42)	23% (22)	22 % (21)	0
The volume of studies currently running within your organisation	3% (3)	40% (39)	19.5% (19)	33.5% (33)	4% (4)

Table 5.11-1shows the perceived awareness of research and the CRN workforce from staff across each responding organisation A large amount

(82.5%, 81/98) felt that staff were very aware or somewhat aware of the presence of a dedicated nurse workforce related to research, and 58% (57/98) felt that staff were very aware or somewhat aware of the importance of research to the NHS agenda. Only 12% (12/98) thought that staff were not very aware of the presence of a dedicated nurse workforce related to research and 21.5% (21/98) thought that staff were not very aware of the current structure of research across the organisation. However, many of the open text comments related to the lack of awareness that respondents felt there was around research and the CRNs. Responses included that awareness was “patchy”, “low” and “not fully appreciated”. Others felt that staff generally “haven’t got a clue” and “are amazed when they come to our department and see what we can offer”.

As with many of the other issues explored within the survey, they was a general feeling that the awareness was varied and very much depended on whether staff had a personal interest or work within research active areas. Comments included that “those staff who are research active / work close with research are very aware but some are not aware at all” and “there is awareness within the specialities of the CRN role but outside of their own area I would say they don’t see the whole trust picture”. Respondents highlighted ongoing efforts of research teams to raise awareness. This included “flyers on the canteen”, “roll up stands in outpatient areas”, “notice boards around the trust showing research activity” and “slots in local and regional conferences”. Many respondents commented they were “working on awareness” and that “awareness now is better than it was 5 years ago”.

Regarding research governance 90% (88/98) agreed or strongly agreed that the CRNs report that adherence to all research governance requirements is high and 80.5% (79/98) agreed or strongly agreed that the CRNs reported that attendance at research governance training sessions was high and team members attend updates as required. Comments were generally positive and respondents felt that “research nurses are very good at ensuring all research and researchers adhere to research governance rules and this is something we reiterate to research nurses all the time”. Generally governance training was

“well co-ordinated and regularly offered” and for larger organisations in general “the infrastructure strongly supports a positive culture”.

Negative comments related to governance compliance and included that it “is a huge challenge to clinical teams”, “becoming increasingly difficult particularly for medical staff” and that “finding time can be problematic”. However, some respondents did comment that it was “easier now we have online training” and that generally “most research nurses are the guardians of good governance and are often involved in ensuring good practice occurs in research”.

As expected and shown in Table 5.11-2 there was a mixed portfolio of research studies at many organisations.

Table 5.11-2 Structure of research portfolio within respondent organisations

Answer Options	**Response Percent (Count)**
Assigned to mixed portfolio of NIHR and Pharmaceutical studies	89.5% (84)
Assigned to studies on the research portfolio only – e.g. CLRN, NCRN etc	33% (31)
Working within a Clinical Research Facility	23.5% (22)
Assigned to single research grant studies	21% (20)
Assigned to Pharmaceutical sponsored studies only	17% (16)
Working on own nursing research	17% (16)
Assigned to other NIHR funded studies – e.g. BRC	14% (13)
Answered question *(Skipped)*	**94 *(17)***

Only 33% (31/94) respondents said that their staff were assigned to studies on the research portfolio (CRN, NCRN etc.) although 89.5% (84/94) said that their CRNs were assigned to a mixed portfolio of NIHR and pharmaceutical sponsored studies.

Therefore, in summary the responses indicated that awareness around research and the CRN workforce was varied and appears in part to be related

to the level of research activity within the individual areas. A small number did express that they felt awareness was “patchy” and that some staff “haven’t got a clue”. However, many teams actively work to raise awareness across their organisation in a variety of ways. Adherence to the research governance requirements seems to be high although some did report that they experienced a few difficulties with this.

5.12. Challenge 6 – Information Technology (I.T) and Infrastructure

This section aimed to examine the impact of technology changes in research both related to I.T changes that had been introduced across the whole organisation (for example electronic patient notes) or research based I.T changes that had been implemented and just involved research related projects. The survey examined whether future plans were in place related to the introduction of either of these types of I.T changes.

Table 5.12-1 I.T changes across organisations. N/A - Not Applicable due to no change in IT provision.

Answer Options	Yes	No	Unsure	N/A	Count
Has there been any organisation wide I.T developments that have been introduced over the last two years? (For example electronic notes).	66.5% (64)	30.5% (29)	3% (3)	_	96
Have you implemented any research based I.T changes over the last 2 years?	46% (44)	50% (48)	4% (4)	_	96
Have new I.T developments across your organisation impacted on the data collection within clinical trials?	32.5% (30)	31.5% (29)	10% (9)	26% (24)	92
Are current I.T developments within your organisation used uniformly across your CRN teams?	48% (45)	16% (15)	13% (12)	23% (22)	94
Are there future planned I.T developments that may impact on the running of clinical trials and research studies within your organisation?	52% (50)	15.5% (15)	32.5% (31)	_	96

In terms of IT developments 66.5% (64/96) confirmed that IT developments had been introduced across the organisation during the previous 2 years. The majority of these developments related to electronic notes and electronic

prescribing. For most respondents these IT developments were currently ongoing and so, for many, staff were working with a mixed system of standard paper patient records and a new “electronic patient record (EPR) system”. Within the responses, 48% (45/94) confirmed that IT developments were uniformly used by CRNs across the organisation whereas 16% (15/94) said they were not and 13% (12/94) were not sure. The few open comments provided stated that they had “different systems of electronic notes in place within some areas” and that there was “a lot of disparate working across the teams” and they were in a “period of transition”.

Implementation of IT changes was not a smooth process and respondents referred to “it being challenging” with “lots of teething problems” as “R&D issues had not been taken into account”. Specific difficulties mentioned included an “inability to provide monitors (of the research studies) login passwords so all monitoring visits must be chaperoned” and “the research team still do not have the correct access to enter data”. The system “was not validated for research and “there was no involvement of research or a strategy to address this”.

Looking at research specific I.T changes, 46% (44/96) confirmed that they had been implemented over the last two years. Many organisations were in the process of, or had just, introduced the EDGE database system. This is an online research management system which supports the collation and oversight of NIHR research. It is used by research managers, CRNs, Clinicians and R&D to actively manage their research within a single system so that information can be better organised and analysed in real time (Edge 2017). Others referred to their “own research tools”, a “new research portfolio database” or specific internal “systems to document research patient care on the electronic patient record system”. At the time the survey was being completed, many NHS organisations were in a period of transition regarding their IT changes; consequently there were diverse responses.

Looking at future I.T developments that may impact on the running of clinical trials and research within an organisation, 52% (50/96) confirmed that they were aware of plans to implement changes where as 15.5 % (15/96) said there was

no planned changes and 32.5% (31/96) were not sure. The majority of comments related to the planned implementation of an electronic patient notes system. Some raised concern that the impact that this would have on research and so hoped to confirm that “research requirements are considered and understood”.

In summary, although over half of the respondents reported that IT changes had been implemented across their organisation, for most implementation was ongoing and so it was difficult to truly gauge the impact it would have on research. Many organisations appeared in transition with new systems such as electronic patient notes and so were using a mixed paper and electronic system. Over half of the respondents confirmed that there were future planned IT changes and 32.5% were unsure. Therefore, if the survey was re circulated now the results may be very different.

5.13. Phase 1b – Analysis of NIHR recruitment data

NIHR recruitment data was analysed in relation to the variables trust type, review and CRN workforce size. Variation in the number of studies undertaken was largely explained by trust type and year. The effect of review of the CRN workforce was not statistically significant throughout (p>0.05). Trust type explained more of the variation than year for three out of four of the models. The recruitment of people was primarily determined by trust type.

Table 5.13-1 Number of studies (intervention, observation) and recruitment of people into observational and interventional studies by trust type, by year, and by whether the trust has undertaken a review.

Effect	**Studies**				**Recruitment(people)**			
	Intervention		Observation		Intervention		Observation	
	χ^2	*p*	χ^2	*p*	χ^2	*p*	χ^2	*p*
Trust Type (6d.f.)	246.20	<.001	222.19	<.001	200.43	<.001	129.77	<.001
Year (5d.f.)	113.27	<.001	247.26	<.001	25.61	<.001	25.29	<.001
Review (1d.f.)	0.00	0.99	0.15	0.70	0.03	0.87	1.61	0.21

Looking at trust type, teaching hospitals conducted more studies and recruited more people into studies than other types of Trust (Table 5.13-2). The number of studies steadily increased up until 2013/14 before levelling off. The number of people recruited into intervention studies peaked in 2012/13, falling in subsequent years (2013/14, 2014/15) and then increasing again in the last year (2015/16) (Table 5.13-2). The numbers recruited into observational studies fluctuated with peaks in 2010/11 and 2013/14. The performance of Trusts who underwent review was similar to those who did not review although the latter recruited over 300 more people into observational studies (1775 versus 1450) during the period 2014/15 (Table 5.13-2)

Table 5.13-2 Estimated marginal means for the following factors: Trust type; NIHR recruitment by year (Year); Review status (Review).

Effect	Studies						Recruitment (People)					
	Intervention			Observational			Intervention			Observational		
	Mean	SE	(95% CI)	Mean	SE	(95% CI)	Mean	SE	(95% CI)	Mean	SE	(95% CI)
Trust type												
Large	54.0	5.0	(45.0-64.9)	42.5	3.3	(36.5-49.6)	679.7	119.9	(481.1-960.3)	1503.4	188.6	(1175.7-1922.4)
Medium	33.0	3.1	(27.4-39.7)	27.8	1.8	(24.5-31.6)	300.2	35.1	(238.7-377.6)	779.2	118.3	(578.6-1049.3)
Small	21.1	1.8	(17.9-25.0)	23.0	1.8	(19.7-26.8)	223.9	35.0	(164.7-304.2)	593.1	181.0	(326.2-1078.6)
Specialist	44.3	17.4	(20.5-95.7)	22.9	3.5	(16.9-31.0)	507.7	110.2	(331.7-777.1)	909.4	191.4	(602.0-1373.7)
Teaching	134.4	12.1	(112.6-160.5)	107.6	10.0	(89.6-129.2)	2092.1	289.8	(1594.6-2744.7)	6906.4	990.2	(5214.4-9147.4)
Wales, Scotland & NI	93.2	24.7	(55.4-156.8)	69.0	13.3	(47.3-100.6)	1971.7	565.7	(1123.6-3459.9)	4289.8	1285.8	(2384.0-7719.2)
Year												
2010/11	43.1	4.3	(35.5-52.4)	30.0	1.8	(26.7-33.8)	535.1	62.0	(426.3-671.6)	1716.7	341.4	(1162.6-2534.9)
2011/12	49.0	4.8	(40.5-59.3)	36.7	2.3	(32.5-41.4)	645.8	79.9	(506.7-823.1)	1268.9	174.3	(969.5-1660.9)
2012/13	53.8	5.1	(44.6-64.7)	40.5	2.5	(35.9-45.7)	828.8	121.7	(621.5-1105.3)	1551.7	210.0	(1190.1-2023.1)
2013/14	59.0	5.3	(49.4-70.5)	48.2	2.7	(43.2-53.7)	728.4	85.6	(578.5-917.0)	1848.3	265.5	(1394.7-2449.3)
2014/15	57.1	4.7	(48.6-67.0)	50.1	2.6	(45.2-55.5)	704.2	79.9	(563.7-879.6)	1835.8	196.5	(1488.3-2264.3)
2015/16	60.8	4.9	(52.0-71.2)	49.8	2.6	(44.9-55.2)	785.1	106.5	(601.8-1024.1)	1486.8	168.9	(1190.1-1857.5)
Review												
No	53.5	4.4	(45.5-62.9)	42.6	2.6	(37.9-48.0)	707.5	83.0	(562.2-890.4)	1774.7	174.1	(1464.2-2151.1)
Yes	53.4	6.6	(41.9-68.0)	41.1	3.4	(34.9-48.3)	688.0	103.7	(512.0-924.3)	1450.3	196.5	(1112.0-1891.5)

NIHR recruitment data was also analysed through a long liner model examining difference in the recruitment numbers and number of studies in each Trust by Trust type, CRN quartiles, type of Trust and whether reviewed or not. For this analysis only data from year 2013/14 that the study was conducted was available for CRN nurses. Table 5.13-3 suggest that after accounting for variation across type of Trust and CRN workforce quintiles the act of reviewing did make a difference to recruitment numbers into interventional studies (x^2=255.38, 1d.f., p<0.001) and a marginal difference for recruitment numbers into observational studies (x^2=3.68, 1d.f., p=.055). However, there was no difference for the number of interventional (x^2=2.45, 1d.f., p=0.11) or observational (x^2=2.30, 1d.f., p=0.12) studies undertaken in the Trust.

Table 5.13-3 Examining the associations between number of studies (intervention, observation) and recruitment into observational and interventional studies by trust type, CRN workforce Quintiles, and by whether the trust has undertaken a review:

Effect	**Studies**				**Recruitment(people)**			
	Intervention		Observation		Intervention		Observation	
	χ^2	p	χ^2	p	χ^2	p	χ^2	p
Trust Type (6d.f.)	146.51	<.001	308.87	<.001	25451.42	<.001	41179.06	<.001
CRN Quintiles (4d.f.)	942.45	<.001	383.41	<.001	12652.49	<.001	19857.6	<.001
Review (1d.f.)	2.45	0.11	2.30	0.12	255.38	<.001	3.68	0.55

There was broad variation in the degree of review undertaken. The survey revealed that fifteen trusts had carried out a full review of their CRN workforce. Therefore NIHR recruitment figures for these organisations were subjected to χ^2 analysis using the methodology previously described. The impact of review was statistically significant for observational studies (p = 0.030) and nearly reached significance for recruitments of participants for interventional and observational studies (Table 5.13-4). This suggests that where a full review has occurred a positive shift in research delivery (study numbers and recruitment) may occur.

Table 5.13-4 Examining statistical associations between study types and recruitment levels with the previously established effects of trust type, year-by-year recruitment levels and review for the15 trusts who undertook a full review.

Effect	**Studies**				**Recruitment(people)**			
	Intervention		Observation		Intervention		Observation	
	χ^2	p	χ^2	p	χ^2	p	χ^2	p
Trust Type (2d.f.)	6.20	0.045	29.01	<.001	11.64	0.003	19.67	<.001
Year (5d.f.)	58.60	<.001	33.75	<.001	39.72	<.001	11.10	0.049
Review (1d.f.)	2.82	0.093	4.73	0.030	3.76	0.052	3.68	0.055

Therefore in summary, the results indicate a mixed picture of the impact of reviewing the CRN workforce structure. When considering trust type and year, there was no statistical difference in whether the organisation was reviewed or not. However, after accounting for variation across trust type and size of CRN workforce the act of reviewing did make a difference to recruitment into interventional studies. Closer scrutiny of the fifteen organisations who had carried out a restructure showed a statistically significant increase in recruitment to observational studies.

Having reviewed the results from the phase 1 survey and NIHR recruitment figures, results from the four organisational case studies will now be presented.

Phase 2: Case studies

Four case studies were chosen from those organisations which had offered in their survey response to take part in phase 2 of data collection. A brief description of each of the 4 organisations is provided below with information taken from the relevant trust website and annual report. A summary and diagrammatic illustration of the current structure of each organisations CRN workforce - based on relevant survey responses - is included. Further information is presented in appendix 21 on the set up of research and the CRN workforce within each of the four organisations (drawing on the detailed phase 1 survey responses and using the 6 challenges of the 'Organising for Quality' framework).

Selection criteria has previously been explained in section 4.8.1 (page 73). The aim of selection was to identify 4 organisations that could be examined through a case study approach in order to provide detailed examples of some current workforce structures. In doing this it is important to ensure that anonymity of all organisations and participants is ensured in order to maintain full confidentiality. This can become more difficult when including larger organisations which may have distinctive characteristics or unique post holders not found elsewhere. Therefore, when describing the participating organisations minimal information has been provided in order to prevent recognition from those who may be more knowledgeable about this topic or the organisations involved.

5.14. Characteristics of four organisational case studies

5.14.1. Case study 1

Case study 1 is a medium sized acute trust in the south of England. It is located in a largely affluent area with relatively low unemployment and above average life expectancy. The main hospital has approximately 600 inpatient beds, including maternity critical care. It provides healthcare services to

370,000 people. The trust was placed in special measures in November 2013 and this was still the case throughout the period of fieldwork.

The trust annual report 2014-15 states “The Trust is committed to the integration of research in clinical practice to provide all patients access to research trials as legislated by the NHS Constitution”. During 2014-15 there were 1006 participants recruited into portfolio studies. Recruitment to NIHR portfolio studies over the last five years is as follows:

Table 5.14-1 Study portfolio and recruitment overview for case study 1

	Interventional studies	Observational studies	Total patients recruitment
2011/2012	38	23	1001
2012/2013	36	29	637
2013/2014	36	33	760
2014/2015	31	32	1006
2015/2016	37	28	768

The organisation has a small CRN workforce of 15 staff. These are comprised of two teams, cancer and generic, as shown in Figure 5.14-1. The generic workforce are at a band 6 and led by the Research Trials Nurse Manager who is at a band 7 level. The workforce has not been reviewed.

Due to the small size of the workforce the research nurses are not integrated into clinical teams as they are in some larger organisations. Therefore the generic team work within numerous clinical teams which are dictated by the studies currently open and recruiting patients. The clinical areas covered change as research studies close and others open.

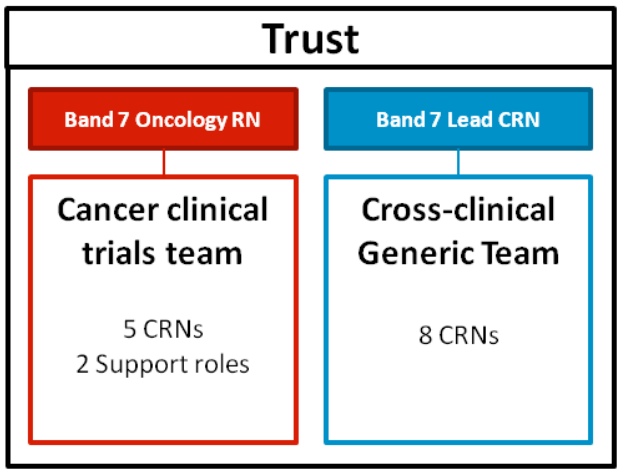


Figure 5.14-1 Organisational structure of case study 1

5.14.2. Case study 2

Case study 2 is a large teaching hospital in the north of England which is located across two main acute sites, has approximately 2000 inpatient beds and employs approximately 16,000 staff. .

The trust annual report 2014-15 states its vision as “To be recognised as the best provider of health care, clinical research and education in the UK” and one of its five overarching aims is “to deliver excellent research, education and innovation”. Recruitment to NIHR portfolio studies over the last five years is as follows:

Table 5.14-2 Study portfolio and recruitment overview for case study 2

	Interventional studies	Observational studies	Total patients recruitment
2011/2012	149	109	4909
2012/2013	169	119	6999
2013/2014	187	148	7645
2014/2015	166	161	7786
2015/2016	193	178	8587

The organisation has a large CRN workforce of 120 staff ranging from band 5 to band 8b and is led by a Lead CRN at an 8b level (see Figure 5.14-2). The trust has three models of CRN employment, one of which involves appointment through their partner university. The organisation initially undertook a full review

of their CRN workforce in 2004. Following this they implemented a structure led by a clinical manager who would take professional responsibility and line management accountability for the CRNs. A group was established to provide the managers with guidance and information to manage their staff. The workforce has been through a number of iterations and there is now a move to a more centralised model with the Clinical Research Facility (CRF) being identified as the central appointing point for new CRNs. A number of mainly historical posts remain within the clinical directorates and so more recently a trust-wide Matron role has been established to provide more operational management of these staff

.

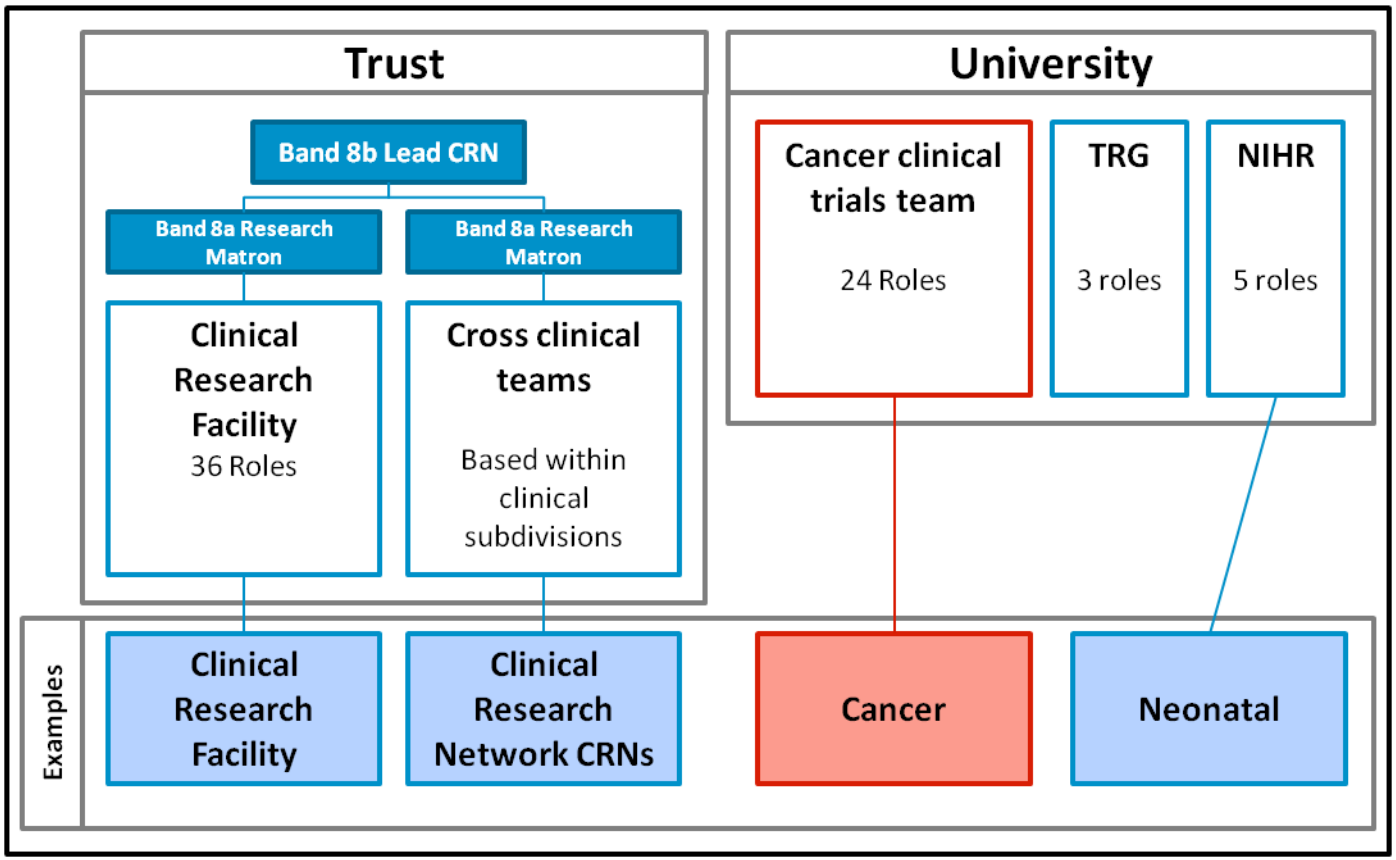


Figure 5.14-2 Organisational structure of case study 2. Abbreviations: TRG – Translational Research Group; NIHR – NIHR funded research group.

5.14.3. Case Study 3

Case study 3 is a teaching trust in central England. The trust is located across three sites, employs 14,000 staff and has approximately 1700 beds The trust currently supports two NIHR Biomedical Research Units.

Recruitment to NIHR portfolio studies over the last five years is as follows:

Table 5.14-3 Study portfolio and recruitment overview for case study 3

	Interventional studies	Observational studies	Total patients recruitment
2011/2012	176	117	8874
2012/2013	211	122	8586
2013/2014	233	149	7184
2014/2015	220	159	9145
2015/2016	208	136	5549

The organisation has a large CRN workforce of approximately 130 post holders ranging from band 5 to band 8a. Most of the post holders are at a band 6 level (73%, 95/130) and some of these work across the research network region although the exact number was not specified. The majority are appointed through the trust but a small number (n= 12) are appointed through their partner university. The workforce is led by the Clinical Research Matron who is at an 8a level (Figure 5.14-3).

At the time of phase 1 data collection the CRN workforce had not been reviewed. However, at the time of my visit the organisation was planning what the Lead CRN referred to as “a big organisational change” which research was planning to replicate although no details were available.

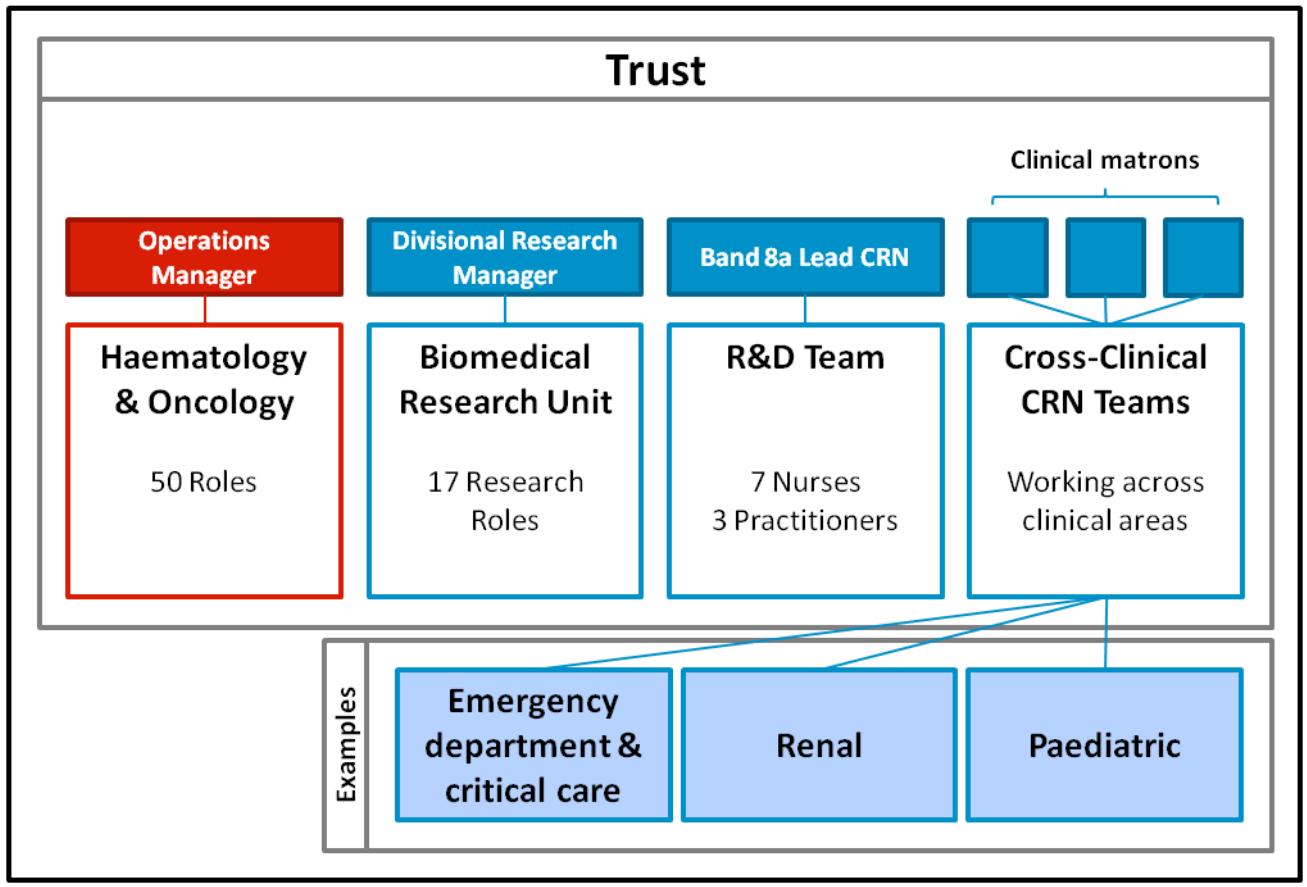


Figure 5.14-3 Organisational structure of case study 3

5.14.4. Case study 4

Case study 4 is a District General hospital (large acute NHS Trust) which serves a population of just over 750,000 in outer London. It operates over two sites and has a total of approximately 1100 beds and employs approximately 5,500 staff over the two sites. It was placed in special measures in December 2013 and this remained the case at the time of data collection.

Recruitment to NIHR portfolio studies over the last few years is as follows:

Table 5.14-4 Study portfolio and recruitment overview for case study 4

	Interventional studies	Observational studies	Total patients recruitment
2011/2012	49	26	694
2012/2013	42	28	572
2013/2014	46	29	2398
2014/2015	48	29	6685
2015/2016	47	29	1171

The trust has a small CRN workforce comprising of 24 nurses which are divided across two main teams, general and oncology as shown in Figure 5.14-4. The workforce was reviewed in 2014 to coincide with the change in the research network structure. Many of the CRN posts became band 6 posts. There had been a decision to develop a Lead CRN post to cover support of the trust wide CRN workforce. This had been discussed in conjunction with the Chief Nurse. However since that time there had been a change in post holder and so these discussions were currently on hold.

In summary this section has given an overview of the CRN workforce within these case studies. A summary table is shown in Table 5.14-5, page 1333.

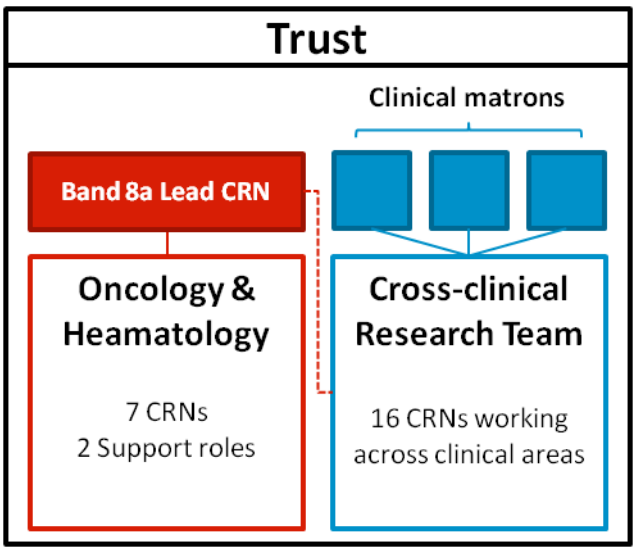


Figure 5.14-4 Organisational structure of Case Study 4

Table 5.14-5 Summary of key characteristics for all case studies

Case Study	Type of Trust	Size of CRN workforce	Level of Lead CRN	NIHR study patient recruitment figures			Number of NIHR portfolio studies		Structure of CRN workforce (Taken from questionnaire survey)
				12/13	*13/14*	*14/15*	*13/14*	*14/15*	
1	Medium Acute	15 nurses	Band 7	637	760	1006	69	63	• Working within clinical teams with non-research colleagues. • Working directly with Consultants on their research studies.
2	Acute Teaching	120 nurses	Band 8b	6999	7645	7786	335	327	• In a structured team within one clinical area • Working in one area in different research teams. • Working within clinical teams with non-research colleagues. • Working directly with Consultants on their research studies. • Working within a Clinical Research Facility.
3	Acute Teaching	130 nurses (approx)	Band 8a	8586	7184	9145	372	379	• In a structured team within one clinical area • Working in one area in different research teams. • Working within clinical teams with non-research colleagues. • Working directly with Consultants on their research studies. • Working independently in one or more clinical teams but not within the team.
4	Large Acute	24 nurses	Band 8a	572	2398	6685	75	77	• Working within clinical teams with non-research colleagues. • Working directly with Consultants on their research studies.

5.15. Case study interviews and focus groups

Phase 2 of data collection involved conducting fieldwork in these four NHS acute trusts. To further address the 7 research questions semi–structured interviews were conducted in each trust with the R&D Director, the Lead CRN and Principal Investigators of studies. A focus group of CRNs was also carried out in each Trust.

Interview questions were structured around the six challenges as identified and defined within the “Organising for Quality” framework. Analysis of the data identified specific themes and sub-themes within the six challenges.

5.16. Challenge 1: Structure

Table 5.16-1 Definition of the structure challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Structure	Structuring, planning and co-ordinating the quality and service improvement effort, and embedding it within the organisational fabric.	Structuring, planning and co-ordinating the Clinical Research Nurse workforce, and embedding it within the organisational fabric to ensure high quality research governance and patient safety.

Four key themes emerged in relation to the structure of the CRN workforce and the research structure in which they work. These were:

- Leadership
- Research delivery
- Lead CRN role
- Challenges and Limitations

Each of these four key themes had a number of sub themes as shown in Table 5.16-2.

Table 5.16-2 Themes and sub themes: Structural Challenge

Theme	Sub theme
Leadership	• Formal support and line management • Quality of senior support for research
Research delivery	• Management structure • Non nursing roles • Team structure
Lead CRN role	• Leadership • Impact • Support for CRNs • Awareness from senior clinical nurses
Challenges & limitations	• Organisational issues • External pressures • Internal pressures

5.16.1. Leadership

Lead CRNs were asked to describe their role and the nature of the line management and accountability arrangements in place. Those that had been able to establish working links with senior management, within nursing and R&D appeared to have been able to develop more effectively within their role and see the benefits including raising awareness of research and supporting CRNs within the clinical environment.

Formal support and line management

Case study 1 was a small DGH that had been in special measures for two years. It had a stable CRN workforce of 16 who had all been in post prior to the arrival of the Lead CRN. There was a feeling that due to ongoing pressures CRNs had become de-motivated and potentially less engaged with the wider organisation. The Lead CRN was a band 7 and had been in post for just over two years. She was not linked in with the wider nursing workforce and so her role felt isolated with minimal support structures in place. Since coming into her current post she had had four nursing managers but felt that she “didn’t link in at all” with senior nurses across the trust and - as a band 7 - “was not autonomous enough to be given the authority to make decisions”. This left her feeling “frustrated” at her lack of authority and the lack of support and feedback she

received. She described herself as never having “satisfactory line management” with no appraisals and just a monthly meeting with her manager. The R&D Director was in his role as part of the remit of the Deputy Medical Director in the trust but he was not an active researcher. He spoke highly of the Lead CRN and agreed that her management arrangements were “a little opaque and not ideal”. Overall he seemed aware of the unsatisfactory support structures relating to her role and confirmed that “she hasn’t really had a clear regular sustained line of professional reporting”. However, he appeared to have no sense of responsibility towards supporting the implementation of an effective arrangement; it had been left to the Lead CRN to find a solution.

In Case study 2 the Lead CRN was at a band 8b level and her role appeared to encompass a more strategic perspective. She had been in post for 4 years and had developed strong links with her senior nurses; she reported directly to the Nurse Director. There was a regular meeting in place where she could provide updates on developments within research and also discuss professional nursing issues if required. She also met with the Chief Nurse twice a year in order to update her on progress within the CRN workforce. The Lead CRN described what she perceived as gaps in the senior accountability of her role, such as she did not attend the senior nurses meeting chaired by the Chief Nurse. However, she was able to articulate the positive outcomes of the leadership structure that was in place. It had, for example, enabled her to help develop awareness of research across the organisation bringing about “a complete sea change” around peoples understanding of research; she felt that “over the organisation there’s a real will to engage in research”. This had impacted positively on the work she had been able to do to develop the CRN workforce of 120 nurses and embed it more effectively across the wider organisation.

In Case study 3 the Lead CRN was at an 8a level but felt that the reporting and accountability for her role was not well structured. The Lead CRN did attend a monthly senior nurse Forum chaired by the Chief Nurse; this had been “good for research and helped raise general awareness around research”. She had also been able to develop informal links with a clinical Head of Nursing (HON) who had knowledge and awareness of research and this had been her main source

of support and linkage with the clinical nurses within her organisation. The HON had discussed with R&D the possibility of taking on direct line management of the Lead CRN. This had not been confirmed due to concerns from R&D that if her post “was completely let out of the R&D structure, then some of the control would also be lost”. The R&D department appeared to be in a state of flux. The R&D Director post was vacant and work was ongoing to make an appointment. The Lead CRN was also due to leave but no decision had been made regarding the future of her role and whether a replacement would be appointed. The department had just undergone an internal review which had concluded that the structure was quite “top heavy”, although no further details were available due to the absence of an R&D Director. The Lead CRN expressed concern that once she had gone her role “might no longer be a priority”.

Case study 4 was a large DGH that was - like case study 1 - in special measures. The Lead CRN was an 8a level but the role did not have a formal trust-wide remit for the CRNs. The post holder was officially responsible for covering cancer research with only informal support for the remaining non-cancer CRNs. The post was line managed within the clinical oncology service; the line manager had come from a large research active organisation and so was supportive and aware of research. He also linked in with the R&D Director so felt that his post was well supported from both a research and clinical perspective; appraisals involved all 3 people. As part of his role he attended monthly clinical meetings within oncology and so was up to date with research activity in that particular service. At these meetings he also received general nursing updates and so had decided not to attend any trust-wide nursing meetings. He explained that “in the cancer area, research is embedded” and “almost part of the patient pathway”. However, for the remainder of the organisation there was less awareness and research was “in a silo, hidden somewhere, doing our own thing”. The lack of any trust-wide initiatives seemed to mean that outside of oncology there was less awareness surrounding research and the CRNs felt less integrated.

Quality of senior support for research

Within case study 1, there was a feeling of a lack of understanding and engagement towards research. The Lead CRN had occasional meetings with the Director of Nursing but explained they comprised of “a little chat about the service” but with no tangible output or direction from the arrangement. She was not invited to the senior nurse meetings and felt that “there is a circle where everything is going on and we just overlap a tiny bit and are not considered”. Overall there was a sense that the CRN workforce were not linked in with the wider nursing workforce; the Lead CRN described this as “often we don’t belong, we are on the edge, on the outside”.

Within case study 2, the Lead CRN talked about feeling “frustrated” as she was aware that “stuff happens that I don’t always find out about through a formal route”. She spoke of her “struggle” to develop effective links with the “clinical side”. However, the structure of her role appears to have at least given her the authority and autonomy to address this. A new Nurse Director was in post and so they were due to meet to “address” what she saw as some of the gaps in her structure. She was also working on a “strategy” that she planned to discuss with the Chief Nurse to further develop nursing accountability within her role. She linked in and had regular meetings with the Clinical Director for the Clinical Research Facility (CRF) where her role was based; this ensured effective senior links within R&D. Her appraisals were done by both of these senior Directors ensuring both effective feedback and communication within these two relationships.

The Lead CRN in case Study 3 was directly accountable to the Deputy Director of Research but this did not appear to be an active relationship; there were no regular meetings. This arrangement had left her feeling professionally “isolated” as she was not line managed by a nurse and so was unable to access support that was “needed with clinical decisions”. She also described her sense of “conflict” as she was often “asked to make decisions that don’t sit well with the nursing side of things”. She had been able to develop informal links with a clinical HON and this had been her main source of support and link with the

clinical nurses within her organisation. She felt this had “very much brought research on the map”. However, the role of the HON was more focused towards Nursing Research and Clinical Academic Careers; the focus on the CRN workforce has been more directed towards supporting them with their academic studies and developing nursing research within this. Therefore, this relationship did not provide active support in developing the CRN workforce or raising awareness of their role within the clinical environment.

Within case study 4 a new Chief Nurse had recently been appointed. The outgoing post holder had been supportive of research and had been looking into the possibility of developing a trust-wide Lead CRN role. However, this work was on hold and at the time of data collection the new Chief Nurse had only been in post for 3 months so there had not been the opportunity to develop any formal links. However, the Lead CRN role did formally link in with the R&D Director and regular meetings took place between the two of them facilitating support for the CRN workforce. However, they did not discuss the development of research across the organisation as he (the Lead CRN) had no official remit to do this.

5.16.2. Research delivery

Management structure

Line management was an emotive subject in most of the case studies especially when directly discussed with the CRNs. Within case study 2 there was a well-structured hierarchy with three research matrons who oversaw the CRN workforce (see Figure 5.14-2 on page 128). This had enabled the development of a well-defined arrangement where all the research nurses had direct links into a more senior CRN. However, across the remaining case studies the structure at times appeared chaotic and undefined and the presence of a Lead CRN did not ensure direct CRN line management for all the research nurses. Some were still line managed by those in a clinical role and there were strong feelings as to the preferred model of support.

Within case study 1 all the CRNs had been in post prior to the arrival of the Lead CRN and had been able to directly experience the benefits of having dedicated management from a nurse who also understood their role and work; this had helped them to feel “more a part of the organisation”. However, within case study 3, some of the CRNs were managed by more senior clinical nurses who left them at times feeling “isolated” with a lack of “interest” in them. This also left them feeling separated from the rest of the organisation and “in our own little world”. In contrast others within case study 3 favoured being managed by clinical nurses who they felt “didn’t know anything about research” as they were then “left alone” and they could “do what they want to”. This was echoed in case study 4 where many of the CRNs were jointly managed by the R&D Director and clinical Matrons. Here they explained that the Matron “tends to just leave us to just get on as long as nobody has complained to her about anything, then she is happy”. They would meet more often with the R&D Director but although this gave some direct research related support it still did not provide a satisfactory arrangement; the nurses appeared unfulfilled. One of them explained she met with the R&D Director but when asking for advice he would say “blah, blah and if it works, fine”.

For some an understanding of research from a line manager was more important than having support from someone clinical. Some felt that “it is better to have someone who understands the particular type of work that you do” and the “nitty gritty” of research. Others clarified this further with the view that a manager needed “to have an understanding not just of research but of the type of research”. They explained this by saying:

> *“Paediatric Research is very different from Intensive Care and the emergency room and it’s different from our Biomedical Research Unit”*
>
> — **CRN – Case study 3**

Some research nurses compared their current line management arrangement with that which had been in place prior to the restructuring of the national research network infrastructure in April 2014. Within this they had been

overseen by a research manager who may have been another health professional:

> *"we have had managers who were not a nurse within the Medicines for Children Research Network and they were very successful. They understood the in-depth studies as well as the basic data collection, so long as nurses were performing and recruiting and doing everything to the protocol, it didn't affect them not being nurses."*
>
> — **CRN – Case study 3**

Therefore, for the CRNs the important factor seemed to be that their line manager understood their role and area as this enabled them to provide meaningful support and advice.

Non-nursing roles

Each of the four organisations were developing non-nursing roles to work within their research teams. However, comments about these roles ranged from being supportive to greater scepticism about what they were capable of doing. Some could see their importance within the research teams:

> *"we have posts in the CRF which are Data Co-ordinators, band 3's. We've got one leading on our flu study under the direction of a band 6 nurse. She's doing really well."*
>
> — **Lead CRN – Case study 2**

However, for some there was a sense of "conflict" between the nursing and newer non-nursing roles because "traditionally there is a research nursing post and now you have someone that is, they feel, less qualified" and "they don't actually do anything different".

Some CRNs appeared to view the non-nurses as a threat to their own role and had quite strong opinions as to who should be doing what within the team, especially when it involved the inputting of patient data into a research

database. CRNs felt that the data “needs to be put in by a nurse” because “as a research nurse that’s part of my role”. There was a feeling that a research nurse would “understand” the data better as “I’m the one who collected it and I’ve written it down”.

There was also a feeling of uncertainty, including from within the teams, especially in case study 1 where these roles were being introduced for the first time. Here the CRNs felt that they were “struggling a bit” trying to understand the new non-nursing role and “just trying to find their feet”. This was because historically they had been doing many of the tasks that the non-nurses had now taken over. However, they did recognise the value of this and commented that “when you look at what it involves there isn’t really any reason why somebody with training who hasn’t got a nursing background, couldn’t do some of these roles”.

The Lead CRN in case study 1 had just recently introduced a non-nursing role and explained her reasons:

> *“I needed somebody that was going to be able to see patients, potentially take on some very low level observational studies but also help the nurses with data entry and also some follow up work. My team were actually not keen in having this person in, they didn’t see the value of it, what was I doing, I ‘had gone mad’, and now they do see the value of it which is great”.*

However, for many there were clear benefits of these new roles. Those overseeing the research could see that there were many “long term benefits”, not least that they attracted “young, keen people” and that they are “cheaper and generally appointed at a lower band”. There was also the acknowledgement that with the evolution of research and a move to a greater use of technology for data capture, new skills were required that the CRNs did not always have. Recruiting young graduates into non- nursing roles was seen as beneficial as they were often “whizzes” on computers and “could do a lot more of the data entry in a shorter time”.

CRNs in the larger organisations (case studies 2 and 3) seemed relatively more open and receptive to these roles and could see the benefit. They could see the overlap in the roles and thought that “they probably do 98% of what we do anyway, it’s just the 2% that we do that they don’t”. There was recognition in the difference in the role and that the CRN was “the one giving the drug and taking the blood”. One CRN summarised it by saying “even though there are 2 aspects that they can’t do there is still 10 aspects that they can do”.

Team structure

Within the four case studies, individual teams of CRNs were situated - to greater or lesser degrees - within an overall structure. For the larger organisations (case studies 2 and 3) these comprised of clinically specific teams of CRNs working solely in one area. For the 2 smaller DGHs (case studies 1 and 4) the CRNs were divided between cancer and non-cancer teams. The non-cancer teams covered numerous areas and in case study 1 the CRNs worked across all clinical areas.

Within all four case studies cancer research was supported by a standalone team. The roots of this are based within the beginnings of the national research network structure as discussed in the background chapter. However, the response to this was at times negative and not always seen as conducive to efficiency. In case study 2 the cancer CRNs were appointed via the university. They came under their own management structure and so were not totally within the remit of the Lead CRN; she could see they were “remote” and “isolated” from the remaining CRNs. She also described a lack of consistency within the workload across the teams and “a huge discrepancy in the amount of funding they got compared to the amount of activity they supported”. From her recruitment figures she was able to see that more patients were put into non-cancer studies than cancer studies but that the funding allocation did not reflect this.

Within case study 3 there was an “established oncology research team” comprising of 50 full time research staff (but not all were CRNs). The Lead CRN

had a cancer background herself and could see the benefit of a specialist workforce within this particular clinical area. However, she also felt that in some areas “you can go to work as a research nurse without being specialist in that area”. She felt that overall the team set up was “not the most effective” and she was “trying to achieve a more flexible workforce”. However, the “workforce is not very moveable” and nurses were “very loyal to their specialities and areas”. At the time of data collection the organisation was being re-structured into a division-led model whereby the pre-existing directorates were being merged into five divisions. The plan was for research to become part of this so that “each division will host their research staff and be division-led”.

However, as in case study 2, there was a discrepancy between the amount of funding allocated to cancer research and the amount of recruitment activity. The Lead CRN reported that “about 40% of our CRN funding goes to cancer but only about 25-30% of recruitment comes from there”. The R&D department were therefore looking to review their funding model in order to grow activity. This would likely affect the setup of the research teams as there was a need to make them more efficient. The Lead CRN felt that currently they had a “structure that is not joined up” with “a lot of different pockets of facilities” and “the money could be used a lot better”.

Within case study 1 the cancer CRNs were separately managed under Oncology Cancer services and so the Lead CRN had no remit to support them. The non-cancer CRNs were referred to as a “generic” workforce but the Lead CRN felt this was a derogatory word and stated that she tried “not to use the G word”. However, she worked hard “to be flexible with the workforce” and so consequently was able to cover a large range of specialties across the organisation. CRNs often worked in more than one clinical area and the Lead CRN in this case study site appeared to be the only one of the four who had achieved some success in involving the Clinical Nurse Specialist workforce:

> *“we have a vascular study for example at the moment that needs a lot of pedal pulses and assessments and scans on the legs and*

we couldn't be able to do that without the Clinical Nurse Specialists".

— **Lead CRN – Case study 1**

Within case study 4, there was a workforce of 24 CRNs but 8 of these were working within cancer. The remainder worked across various clinical areas but each CRN only worked within one clinical area. This meant that currently some areas did not have any research activity as there was no CRN to support it. The Lead CRN was himself based within cancer and so was more supportive of this model having spent most of his career working within this area. He commented that as a trust they had been "growing research for a number of years" but had "got to the point where we couldn't grow anymore and so are concentrating on delivering best quality research".

5.16.3. Lead CRN role

Two of the sites (case study 1 and 3) had not had a Lead CRN before, whereas in case study 2 the post had been established for just over 10 years and the current post holder was the second person to hold the post. The final site did not have a dedicated trust-wide Lead CRN and so the Oncology Lead CRN was trying to fill this role.

Leadership

The perception that having a dedicated senior research nurse to oversee the running of research within an organisation had a positive impact was common among the individuals interviewed. Positive outcomes of the role related to the strategic and symbolic leadership it provided such as the post holder having been able to "draw things together" and "manage the capacity".

Across the four case studies the Principal Investigators (PI) all expressed their support for the Lead CRN role. In developing a structure one PI (case study 1) felt the Lead CRN had "built up a fantastic team" and done an "impossible job". He remarked on the "huge change" that had occurred since the Lead CRN took up post and how the CRN workforce structure now worked "very well". Many of

the PI's described how they now liaised directly with the Lead CRN when considering whether to set up new studies and how "having someone with experience makes a big difference" to the running of their studies.

In this same organisation (case study 1) many of the CRNs had been in post for a number of years and so were able to reflect on the difference that the Lead CRN role had made. Before the post holder had arrived they had "tried to do things" themselves but "that wasn't the done thing". One CRN remarked that "we couldn't even order pens, we were really stuck for a while. So having her (the Lead CRN) has definitely improved things".

Impact

There was general agreement as to the positive impact that the role of the Lead CRN had, firstly, on the whole research process and, secondly, the nature and extent of the support that research nurses received. Examples were given of some of the significant errors or mistakes that had occurred prior to the appointment of a dedicated Lead CRN. These included, for example, a governance breach where a clinical nurse had misunderstood instructions and removed all clinical information from the notes of a patient who was involved in a study as well as a lack of proper oversight for studies. A research nurse at case study 1 commented:

> *"the day I walked in I couldn't actually believe what I looked at. I mean there were some studies that didn't even have site files and recruitment logs were bits of paper randomly put in a file. I mean it was shocking"*

There were also observations that a dedicated Lead CRN post had enabled research to run more efficiently. The PIs leading research projects saw the role as "essential" and described the CRNs working under her as "faultless in their efficiency" and providing a "seamless" service which overall "works really well". They explained that for research "a different kind of discipline is required" in

order to ensure that the projects run smoothly. The Lead CRN has been able to develop a team that had “got that discipline and it makes it much better”.

Support for CRNs

Another beneficial impact of the Lead CRN role was the level of support that the research nurses received in being able to carry out their role effectively. One felt that since the Lead CRN had been in post they “had learnt so much” and it was a “wonder we didn’t do anything disastrous” before. One CRN likened her experience before the Lead CRN’s arrival “as the blind leading the daft”.

CRNs across all organisations commented on feeling “supported” and “focused” upon. It was felt the role was also able to “open doors” and speak on behalf of the nurses, especially if this involved an awkward conversation. One nurse commented “I didn’t feel I was in a position to say we can’t do that study but she can do that” (case study 1). This was also acknowledged by the Lead CRN; she wanted her nurses to “take the lead and feel empowered” but was also aware that her role provided them with “back up” when they were “not feeling confident to deal with something”.

P.I s in two of the case study sites (1 and 2) commented on the importance that having someone who was knowledgeable and with previous “experience” who “has done the role (of the CRN) before”. They felt that this then gave the CRNs “someone with experience to guide them” as they often arrive in the role “without previous experience”.

There was also a recognition of the importance of having a Lead CRN who was able to line manage the research nurses. It was felt that this would ensure “a very clear performance schedule” because “to line manage research nurses you have to have been a research nurse”.

At one of the sites visited the Lead CRN was moving to another post. At the time of the fieldwork visit there were no plans in place to replace the post holder; this was causing a large amount of concern amongst all members of the research team. The research nurses felt they would be “missing out” and that it

was sending a “mixed message” about the importance of research across the organisation.

Awareness from senior clinical nurses

The lead CRN also provided representation at senior nurse meetings across the organisation. In some case study sites this had led to an increase in the awareness of research from this nursing group - including the Chief Nurse - and the CRN role. Case study 3 had a relatively new Chief Nurse who was seen as “supportive” with some understanding of research; CRNs here felt they had “visibility” from a senior nursing level and that their role was “seen as important”.

The role had also enabled links to be developed within senior nurse peer groups across research and clinical services. Within one organisation (case study 2) the Lead CRN had enabled the research matrons to be part of the duty rota that provided site cover. This was seen as having a positive impact:

> *“I’ve pushed to do it. We’re seen as equals because we muck in and do the rota just like every other Matron. Its challenging but I think it’s beneficial to us that sit in this lovely research bubble. It increases awareness”.*

However, individuals in other sites also described struggles with achieving links with more senior nurses across their organisation:

> *“I don’t link in at all. I see her once a month and we have a little chat about the service. Often I am not autonomous enough to be given authority”.*
>
> — **Lead CRN – Case study 1**

5.16.4. Challenges and Limitations

The success of the different research nurse structures observed in the four case study sites appears to have been impacted by various local challenges and limitations.

Organisational issues

The organisations studied had a variety of models in place that supported the CRN team. However, one P.I described their structure as “an accident in history” (case study 1) and agreed that if they “could start with a blank piece of paper today you wouldn’t have what we’ve got”. He described it as a system “that’s evolved reactively depending on what’s there and it’s different across the whole organisation”, adequately summarising the situation in the other case studies. The Lead CRN in case study 3 explained:

> *“this structure that we’ve got in place now is something that has historically been there”*

Case study 2 had undergone a re-organisation process about 10 years earlier and put a desired new structure in place. However, even this organisation acknowledged that a small section of their workforce (cancer research) had not been included in their restructure and it consequently remained within a “historical” model which “just doesn’t work”. This model involved appointing the CRNs through the university which the Lead CRN felt left them “remote” and “isolated”. This approach was with a result of the initial establishment of cancer research networks in 2001; the model established then had remained for this clinical area despite further development and changes across the rest of the workforce. The Lead CRN described it as her “biggest challenge” and - despite some of the ongoing work to address and change this structure - she recognised that “it had been a very tricky and political” project.

Interviewees in other case study sites also described how the arrangements for cancer research were different and how - at times - there was a feeling of conflict with the remainder of the CRN structure. In case study 1 the cancer CRNs were managed under cancer services and not R&D like the rest of the nurses. The Lead CRN described cancer as “a bit precious at times” and felt that “sometimes there is not always the appreciation of the non-cancer side of the service”. Cancer CRNs did not come under her remit which had led to some “competition between the 2” teams. In case study 4, the cancer research nurses

made up a third (8/24) of the total research nurse workforce; this was the only area to have a dedicated team. Other areas shared a research nurse as their role was seen as more generic and would cover more than one clinical area. The Lead CRN here also only officially covered cancer with no trust wide remit. The post holder helped supported the non-cancer CRNs but had “no mandate, just consultation” so could only offer informal support.

External pressures

Two of the organisations (case study 1 and 4) were in special measures at the time of data collection. This appears to have had a big impact on research and its relative importance:

> *“there is no awareness of the role in terms of looking at the future at the moment and that would be an inadvertent consequence of being in special measures and therefore you are focusing on certain things.”*
>
> — **Lead CRN – Case study 4**

> *“I came here in September and that was the month we went into special measures, so establishing myself in a new role in this environment has been particularly challenging because the emphasis has not been on research.”*
>
> — **Lead CRN – Case study 1**

However, for some there was a sense of hope that research would improve once the external pressure had been resolved. The Lead CRN in case study 4 remarked that “once we are out of special measures, the discussions around the table will be different and they will look into the future and we can start living”.

Other external pressures were also mentioned. Interviewees in one organisation stated that some of their clinical services had now been contracted out to “social enterprise” schemes and so groups of patients had been lost (for example in case study 1 the diabetes outpatient service had been contracted out). As

research had not been discussed at the point of contract negotiation, the CRNs were not able to approach these patients for studies and so no diabetes studies could be run. This directly impacted on the potential clinical areas from which research nurses could recruit.

Internal pressures

Interviewees also cited the impact of wider financial pressures on the research infrastructure and the "difficult economic climate". One PI commented that:

> *"we are £40 million overspent. In that context I can't imagine it being a fertile ground for blue sky thinking about research nurses".*
>
> — **Principal Investigator – Case study 1**

In this context research activity was perceived as being a very low priority for members of the trust senior executive team:

> *"If you asked the Chief Executive of this trust to list in order the things that are important to this trust it would be ambulance waits and the 2 week targets and the 100 day waits and right down on the bottom of the list, somewhere on page 3 would be research. It is not seen as high priority"*
>
> — **R& D Director – case study 1**

Funding for the research nurse workforce was an ongoing concern especially as NIHR funding is calculated on the previous year's recruitment figures. Any constraints which limited the ability of CRNs to recruit to studies would directly impact on their future funding. Many of the CRNs understood this and realised that "if we don't recruit we don't exist as we are not there to fund the clinical budget".

5.17. Summary of key findings: Structure Challenge:

Leadership:

- Effective links with Senior Managers both within research and the clinical areas helped in the support of the CRN workforce and the general awareness around research.

Research Delivery:

- An effective line management structure for the CRNs involves someone who understands their role and clinical area.
- Initial lack of understanding regarding the benefit and input of non-nursing roles but this reduced over time.
- Differences in team structures are related to the size of the CRN workforce. The structure of cancer research teams is based on a historical model which at times causes conflict.

Lead CRN role:

- Importance of a dedicated senior research nurse to oversee the efficient running of research.
- CRNs feel better supported and more empowered within their role.
- Role provides a senior link into nursing across the organisation helping to raise awareness of research.

Challenges and Limitations:

- A historical and reactive growth of research and the CRN role has at times resulted in a less than ideal structure.
- External and Internal pressures can have a negative impact on the success of research across the organisation.

5.18. Challenge 2: Culture

Questions aimed to explore the culture of research across the organisation including an understanding of the value and importance ascribed to it; support from those in the clinical environment was also explored.

Table 5.18-1 Definition of the culture challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Culture	Building a shared understanding, commitment and community around the improvement process	Building a shared understanding, commitment and community around research and the CRN workforce

Five key themes emerged in relation to the culture of research within the case study organisations. These were:

- Clinical perspective on research
- Interaction between research and clinical staff
- Value of research across the organisation
- Physical space for CRN work
- CRN Uniform

Table 5.18-2 Themes and sub themes: Cultural Challenge

Theme	Sub theme
Clinical perspective on research	• Understanding • Lack of time and competing priorities • Managers as gate keepers • Opportunities to support understanding
Interaction between research and clinical staff	• Benefits • Favours and 'bribes' • Embedding & integration of research nurses
Value of research across the organisation	• Importance from clinical colleagues • Lip service
CRN Uniform	• Professional Identity • Patient perspective • Lack of consistency

Each of these five key themes had a number of sub themes as shown in Table 5.18-2.

5.18.1. Clinical perspective about research

This theme and its sub themes largely emerged from the question that was asked to all interviewees: “What is the importance associated with research across your organisation and how much value is put on it?” The responses indicated that there were numerous factors that influenced levels of awareness, understanding and attitude amongst the clinical nursing staff who were working alongside research nurses. There was also a variety of experiences within each organisation.

Understanding

This theme relates to both a lack of understanding about the research process and the research nurse role; all levels of nurses openly admitted their lack of understanding. CRNs expressed frustration as their colleagues “they just don’t know how research works and they don’t know what a research nurse does”. In one organisation the Director of Nursing had referred to the research nurse workforce as *“feral”.* The research nurse further explained:

> *“we weren’t feral because we were doing crazy, stupid things but it was because no one knew what we were doing and that is a real problem. So we were a part of the nursing workforce and yet the senior nurses hadn’t got a clue what research nursing is”.*
>
> — **CRN – Case study 1**

Lack of understanding from senior nurses was perhaps inevitably seen to have had an impact on the support they were felt to provide to CRNs. The R&D Director in case study 4 felt the CRNs were “very poorly supported”. due to a variety of factors including “one, she is too busy, two doesn’t have the knowledge and three, they don’t understand and hence they do next to nothing about it”. There also seemed to be concern from senior nurses that if they supported research it would impact their workload and so consequently they

“won’t touch it with a barge pole because they think it means more work for them”.

Such lack of understanding appeared more common in the District General Hospitals (DGH) (case studies one and four) as the clinical Matrons here were often line managers for the CRNs with minimal input. The CRNs felt that the clinical Matrons “literally left me on my own because a lot of the speciality is not her field”. However, it was not total abandonment as there was a realisation that the Matron was “willing to delve in if I have an issue on the nursing side of things”.

In many organisations CRNs themselves recognised that other staff generally had a lack of understanding and “zero interest” about research:

> *“people don’t understand research and they are not aware. Even one of our executives didn’t know research is a core principle of the NHS”*
>
> — **R&D Director – Case study 1**

> *“the staff know so little about research or what our role is that they don’t really understand and it’s certainly not a priority”.*
>
> — **CRN – Case study 1**

At times this lack of understanding about the role appears to have also led to a feeling from the clinical nurses that the CRNs were a possible threat, stemming from the amounts of time that research nurses were often able to spend with their patients. Staff viewed the care within research as different and noted that patients would approach the research nurses first in the event of any problems or clinical concerns. At times the specialist nurses felt they “got a bit side lined”. This was often because “the research patients were ‘phoning the research nurses” first. At other times differences in the patient care delivered within the context of research studies was noted:

> *“I needed a meeting with the Service Manager because some of the staff thought that the research patients were getting a better*

deal than the other patients, and they didn't like that, they thought it was wrong. It took some time to explain to them that these patients were having standard care".

— **Lead CRN – Case Study 1**

As the opinion above illustrates, much of the lack of understanding centres on the CRN role. This sub-theme came out quite strongly especially within the focus groups where participants variously described ward nurses as perceiving the role as "a cushy number", "they think we just wander around with a diary" and "not even proper nurses". But as two CRNs explained:

"there are many days when some of us don't have lunch because we are too busy. We stay after hours to do sampling in the lab, and they just don't see that side of things; they think it's all paperwork and sitting down and that's it"

— **CRN – Case study 4**

"Its lack of knowledge, just because we don't work on a ward doesn't make us any less busy".

— **CRN – Case study 3**

However, factors external to the organisation were also seen as influencing understanding of the CRN role. This particularly related to the 2 DGHs who were both in special measures and where the CRN role was "viewed as bringing something extra that's not required". This seemed to mean that there was "no positive active support from the top down", with "resistance" and "ambivalence" further down the organisation hierarchy.

Lack of time and competing priorities

This was felt quite strongly by the CRNs across all case studies who felt that the clinical nurses "can see all the positive benefits" of research but often view it as an additional task that could be left undone in the context of an increasingly heavy clinical workload. There was a strong feeling that frontline NHS staff are currently so busy that there is no time for research:

> *"I think everyone is really, really busy. And I think across the NHS everybody is expected to do more for less and I think it is just something else that they really don't want to engage in because they have already got such a lot on their plate".*
>
> — **CRN – Case study 1**

Some more senior research staff felt that research was seen as being in conflict with clinical service provision.

> *"senior nurses find themselves in a very challenging position because they are in positions where there is a huge conflict and tension between their professional obligations and their managerial obligations to deliver the service. I am sure they would say that they are very supportive of research and say that they would support people doing research but in brackets they would say as long as we have managed to do all the other things first, close brackets"*
>
> — **R&D Director – Case study 1**

Managers as Gatekeepers

There was a feeling among some of the CRNs that managers of clinical nurses were preventing their staff from supporting research and being very "protective" about what their role included:

"She literally said 'my girls do enough, you can do the research but they're not doing anything on it'. It's almost like the gate keeping thing, she won't let you in".

— **Lead CRN – Case study 1**

"there are some senior nurses on the ward who put the cross sign up by the door, don't come near us, because they think we are going to make them more work"

— **CRN – Case study 3**

However, it was acknowledged that this may often have been a protective action from the manager to prevent their staff from having even more work to do.

Opportunities to support understanding

When discussing the difficulties that CRNs face when carrying out research within clinical services there was a strong feeling from more senior research nurses that CRNs should take active steps in order to facilitate clinical staff having a better understanding of research and the CRN role:

"there's something pre-reg that we need to be showcasing what research nursing and nursing in research does"

— **Research HON – Case study 3**

"there's a lot more we could do with the ward nurses to get them to understand what the role is, that it's not just swanning in and swanning out"

— **Lead CRN – Case study 3**

This then led to further discussions about some of the remedial steps which had been taken in some of the case study sites.

5.18.2. Interaction between research and clinical nurses

This interaction is important because in order for research to run smoothly within the clinical area the CRNs must be able to work alongside their clinical colleagues, often within the same outpatient clinic or patient area and/or along the same patient care pathway.

Benefits

Many of the CRNs commented on the benefits that they felt their presence brought to the busy clinical areas including such activities as “take on care, put up the drug and take blood”. The CRNs remarked that the clinical nurses appreciated this as they did “see it as coming in and being helpful as we are taking the patients off their hands for a couple of hours”.

The CRNs in case study 1 also explained that the clinical nurses appreciated the support that they gave to patient care because it “takes some of that pressure off them”. A PI in one of the case studies highlighted the direct benefits that research offers patient care, especially in relation to drug treatments which otherwise would not be available:

> *“the commercial trials allow us to give drugs that we would never be able to give in the NHS for another five years. We love using those drugs.”*
>
> — **Principal Investigator – Case study 4**

Access to new drug treatments administered within research studies also means that when the same drugs came onto the market, the CRNs may often be the ones who train the clinical nurses in how to administer them:

“quite often it is us who train the clinical nurses because we’re pioneering the using of drugs in trials well before they’re marketed and when the drugs get marketed, my research team will educate them”.

— **Principal Investigator – Case study 2**

There was also a feeling that the presence of the CRNs within the clinical area allowed mutual support between themselves and their nurse colleagues. CRNs spoke of this as a “two-way thing” with each learning from the other. Direct benefits to studies were also recognised; CRNs were able to identify a link between successful study recruitment and “engaging with the clinical staff especially the nurse specialists”. They highlighted that nurses would contact them if a patient arrived who may be suitable for a study.

Favours and ‘Bribes’

CRNs also talked about doing “favours” for the clinical nurses in order to integrate themselves with the wider team. It was felt that this would them give them an “equal footing” with their clinical colleagues. The CRN would “muck in” with the workload as this would help to “open up lines of dialogue” which may assist in the future if they needed a favour in return.

One of the Lead CRNs felt that the benefits of this were apparent and thought that “the clinical nurses are more likely to do something, go the extra mile, if they’ve had something back”:

"so we quite often will go out and do favours. It's like 'I'm not busy at the minute do you want me to take that blood?' So when we need a favour back we've generally got them onside"

— **Lead CRN – Case study 2**

Concern was expressed by this Lead CRN as to whether this amounted to being "manipulative" but overall she recognised that it is about "working as a team because it brings such huge benefits".

CRNs also referred to "bribing people with sweets" or "thanking the nurses" with chocolates or cakes which helped gain support for their studies or reward the assistance they had received. The reciprocal nature of this was also highlighted. The CRNs felt that the clinical nurses were often very "accommodating if we need to ask a favour". Overall it was felt that it was "give and take" between everyone.

However, this level of collaboration was not apparent in all the case study sites; other CRNs found that if they were not integrated into the clinical service to the same extent as their colleagues, this meant that they were not " there all the time" and so it was more difficult to build up favours.

Embedding & integration of research nurses into clinical areas

Many of the teams felt that the success of the research was helped by how much time they were able to spend within their clinical area. Some of the research nurses spent all their time working within a department and so felt that research had a presence and was integrated and part of that team:

"in our team we spend a lot of time in the department , and in their induction research is always highlighted. I think because we are in there quite a bit they really see us as part of the team".

— **CRN – Case study 3**

Others acknowledged that those nurses who had previously worked in the clinical area and then moved across to a research role within that same area

found integration with the clinical team much smoother. The Consultants favoured this and remarked that because she "was a long time clinical stroke nurse, she has a good rapport with the rest of the stroke team" and "she came from the clinic and so everyone knows and she works very well with the team". However, where clinical services were dispersed, it was very difficult to become truly integrated as often the clinical staff were "quite segregated". An example given for this was renal medicine where "the wards are one thing, outpatients are another, haemodialysis is another and peritoneal dialysis is another".

As outlined above interactions between the clinical and research staff was also helped if the CRNs were seen to help out in times of extreme need:

> *"when we have had a nursing and clinical crisis the research nurses have undoubtedly contributed to the clinical service by being part of the clinical team and stopping being research nurses for a period of time"*
>
> — **R&D Director, Case Study 1**

However, some CRNs were quite cautious about becoming too integrated in case it detracted from their research studies. It was pointed out that it is always important to remember that the CRN role is aimed at supporting research and the outputs from that. As one Lead CRN explained "if my girls aren't doing research we aren't getting bums on seats and therefore that impacts on my funding".

Expressing similar sentiments, some PIs felt that if "you embed the nurses even more" there was a danger of losing them to the clinical service as they would be asked to "support the service gaps". In this case it was viewed that "there are clear benefits in reminding people that they are wearing a different colour dress and there to do research and not provide a service".

5.18.3. Value of research

This theme and its sub-themes emerged from questions concerning "what is the importance associated with research across the organisation and how much

value is put on it?" There was a broad recognition of the importance of research within the wider NHS; nonetheless, some organisations seemed to struggle with integrating research into the day to day business of patient care.

Importance from clinical colleagues

Although there was recognition of its importance some interviewees felt that the organisation "did not put enough focus on research" as it is just a "niche area". Researcher's felt it was "fundamental" and "in my opinion, everybody's business". However, in some organisations, especially the two in special measures, the importance and value of research was relative low with respect to other priorities. Research was "not a priority" and because the focus was on "sorting out people at the front door, they are not going to be thinking about research which might give rewards 10 years down the line". For many the real priority was seen as the "day to day balancing of the books".

The PIs could gauge the importance that they felt the organisation assigned to research. In case study 2, a PI had been supporting research for 15 years and so had developed a successful research service alongside the clinical service. He explained:

> *"the ethos really is that every patient who we see clinically potentially could be a research subject, and so it is our duty to offer our clinical patients the opportunity to take part because that opens different avenues to them otherwise not available".*

Within the same organisation another PI felt that at times the importance assigned to research was "a sort of nominal value in name". He continued that he felt there was a recognition that "research forms part of being a successful trust" but that generally "other clinical priorities take precedence and you can see why".

Lip Service:

Although the value and importance of research was acknowledged, many participants still felt that it was never high on the priority list. A lot of the time the support it received was ascribed to lip service:

> *"every mission statement of any trust has research as top priority but like every trust there is a big financial squeeze. I think surviving financially is probably more important than research excellence".*
>
> — **Principal Investigator – Case study 3**

> *"what you are saying is we are really engaged in research, it's really important, we want everyone to do research but you're not actually backing that up with someone who can facilitate that. It gives a mixed message"*
>
> — **CRN – Case study 3**

The R&D Director in case study 1 acknowledged that research was often used as an "opportunity to sell the trust and something that was good to talk about" but that the reality was very different and the support was not always there. This was sometimes felt to be due to completing priorities so there was a feeling that people would "talk about research but wouldn't necessarily walk the walk". He felt that overall "it is one of those things that is really valued but without necessarily being supported".

5.18.4. Clinical Research Nurse Uniforms

Many of the research nurses had very strong views on whether they should wear a uniform and, if so, what this should be. This had not been anticipated prior to the fieldwork commencing and initially arose in the first research nurse focus group. As their opinions had been so strong this issue was then explored further in all the subsequent focus groups.

Professional Identity

A lot of the feeling about uniform was related to how it made them feel, confirming their professional identity and role as a nurse. CRNs commented that “I think we all kind of base our identity as a nurse”; and that by wearing a uniform it “makes us nurses” and if you “didn’t wear a uniform you weren’t seen as a nurse”. So that overall it was a felt that the uniform was “embedded in that nurse culture” and “very, very important as it’s the person you are”.

Patient perspective

Linked to their feelings around professional identity was the response CRNs felt they received from patients. Many felt that the reception they received was better when they were in uniform:

> *“I think patients can relate to us better, rather than in mufti. It’s just more professional … I think if they see you in uniform the patients respect you”*
>
> — **CRN – Case study 4**

The colour of the uniform was also important. Some CRNs wore the specialist nurse uniform of their organisation. Some felt that if the colour of their uniform linked in with the colour of more senior nurses across the organisation, then this led to a different approach from patients and more respect for them:

> *“if you are walking around the hospital people usually stop you particularly if you’re in dark blue, ‘excuse me sister, can you help me find’ whatever? I think it does give us a level of respect all wearing the same”.*
>
> — **CRN – case study 4**

Lack of consistency

There was no consistency regarding the uniform within organisations. However, the wearing of uniform was often related to the influence that the Lead

Research Nurse had in initiating the practice. In case study one, it was noted that the Lead CRN “initiated” the uniform on her arrival. In case study 3 the Lead CRN had been seen to be “working very hard to push the uniform side of things” and put all the CRNs in “one uniform, to be recognised”.

Within organisations, some research nurses would wear the uniform of their clinical nurse colleagues especially if it was a designated area such as the emergency department. Other nurses worked in a distinct research area such as a Biomedical Research Unit (BRU) and so wore a uniform attached to this setting.

None of the case study organisations had a consistent practice regarding their uniform for research nurses. One of them was having a trust-wide review of their nursing uniforms and the research nurses had been offered a red uniform to wear. This evoked a large amount of discussion primarily based on colour and cost.

> *“a dedicated research nurse uniform, so that’s very new. I don’t know whether we’re going to do a massive roll out or are we going to start putting new staff in it because we haven’t got much money”.*
>
> — **Lead CRN – Case study 3**

The CRNs within this organisation (case study 3) displayed a mixed response to the recent decision of a trust-wide uniform for them. It was felt that it may “alienate our team because we would be in a different colour”. When considering a red uniform some nurses stated that they couldn’t “think of a worse colour to wear”. Whereas, others recognised the benefits of a bright dedicated uniform. Those already wearing it had found the response “phenomenal “and felt that it had given them “real visibility” within the trust. They recognised that it “helps going onto wards and things as everybody knows who we are”.

Increased visibility of the CRNs due to their uniform was also noted at another organisation (case study 1). On her arrival the Lead Research Nurse had introduced a green uniform for her small team of research nurses and this appeared to have had a positive impact:

> *"I would say that the unit that she set up with the green uniform seems to work very well and if she thinks that the green uniforms are a major contributor of that I will sign up to it."*
>
> — **Principal Investigator Case study 1**

—

> *"That helps our patients as well, especially that first meeting because if you are having to meet them in the main reception area or something like that you might not know who they are, but actually they will see you in green so that's quite good."*
>
> — **CRN Case study 1**

Also linked to the uniform was the issue of cost and for one group of university funded research nurses (case study 3) this had led to them having no uniform despite their desire and request to have one. This meant they worked alongside their trust appointed research and clinical colleagues:.

> *"I would never have dreamed of not wearing a uniform. I hate wearing my own clothes. I feel very exposed wearing my own clothes when I am dealing with patients. I feel very exposed going into a ward. I would feel better in a uniform, but it's not going to happen, no funding. We are funded differently and therefore our uniform is our lanyard around our neck"*
>
> — **CRN Case study 3**

The negative impact of this was felt to be heightened as their trust appointed CRN colleagues worked across two different sites and so many of them had two uniforms. When they changed site they were expected to "change our uniform and go into the nurse practitioner, the royal blue".

5.18.5. Summary of key findings: Culture Challenge

Clinical perspective on research

- Many perceived that clinical nurses do not fully understand the CRN role.
- Current pressures within the NHS adversely impact on the amount of support given to research.
- Senior nurses feel protective of their staff and act as a gatekeeper as what they see as additional workload.
- More could be done to promote a better understanding of research and the CRN role.

Interaction between research and clinical nurses

- CRNs have a beneficial role within the clinical environment and can support patient care.
- CRNs often carry out favours or ‘bribes’ within the clinical environment to help promote research and gain further support.
- Working alongside the clinical team either currently or in the past aids the embedding and integration of CRNs into that team.

Value of research across the organisation

- Broad recognition of the importance of research across the NHS.
- However, some struggle with integrating research into the day to day business of patient care.
- There appears to be wider consent but not individual co-operation within areas.
- Support received was sometimes ascribed to lip service.

CRN Uniform

- CRNs stressed the importance of their uniform related to their feelings of professional identity.

- CRNs felt they received a better response from patients when wearing their uniform.
- There was a lack of consistency across organisations related to the uniform worn by CRN teams.

5.19. Challenge 3: Education

Table 5.19-1 Definition of the education challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Education	Embedding and nurturing a continuous learning process in relation to quality and service improvement issues, including both formal and informal mentoring, instruction, education and training, and the acquisition of relevant knowledge, skills and expertise.	Embedding and nurturing a continuous learning process for the CRN workforce in relation to high quality research governance and patient safety including both formal and informal mentoring, instruction, education and training and the acquisition of relevant knowledge, skills and expertise.

Lead CRNs were asked to describe how the education for CRNs was structured and supported within their organisations. During the focus group the CRNs were also asked to comment on the educational support they received towards their role.

Two key themes emerged in relation to the structure of the CRN workforce and education. These were:

- Quality of Leadership
- Culture

Table 5.19-2 Themes and subthemes for the challenge: education

Challenge	Theme	Sub Theme
Education	Quality of Leadership	• Attitude of senior leaders
	Culture	• Educational Structure • Management support • External influences

Each of these key themes had a number of sub themes as shown in Table 5.19-2

5.19.1. Quality of Leadership

This relates to leadership both within research and across the organisation.

Attitude of senior leaders

There was a link between the attitudes of senior leaders and the Lead CRN as to the focus of educational support provided. Within one of the smaller organisations (case study 1) the R&D Director demonstrated a lack of engagement towards the education of the CRNs. He saw education as being within the remit of the Lead CRN and stated that the he would trust her (the Lead CRN) "to provide the education that they need in order to fulfil their roles". He also appeared to demonstrate some apathy towards the CRN workforce and felt they were not engaged or motivated towards education:

> *"a number of then have become research nurses for a variety of reasons. Seldom because they are fascinated by research and some because it offers them a work / life balance opportunity and they may not be interested in taking that further. They are happy contributing that way without necessarily developing themselves"*

This was also demonstrated by the Lead CRN when she described her nurses:

> *"I haven't had any of my team ask me about a degree yet. When you meet them you will see what I mean. 2 or 3 have got young families so it's not appropriate at this time. One just comes to work; I don't really know why to be honest with you. Two of them would say they are too old. So it's not that I don't support them".*

However, one of her CRNs had arrived in post having completed a Masters degree. She was not convinced of its benefit and remarked "it's quite interesting

having one who is so academic and can show off a piece of paper but we can see the practical skills are not there".

In contrast, case study 4 was a larger DGH that was also in special measures. Here, however, the attitude was very different. The R&D Director felt it was important to encourage his staff to undertake academic studies and remarked that he was "happy to fund anything within reason". However, he also ensured that the drive to develop came from the individual themselves. He was aware that "you can't push anyone into education" and that individuals "need to do it on their own accord". He was very supportive of the whole CRN workforce and stated "If I don't invest in my staff then nobody will".

Attitude towards education was clearly linked to the behaviour of the Lead CRN and whether they were a role model and valued academic progress. Within case study one the Lead CRN had not done any further academic studies herself. When asked whether she discussed academic development with her staff she appeared to have dismissed their interest in it and remarked "nobody has come up to me" to ask about it.. She agreed that for her team "training was more related to the role of the post holder rather than looking at ongoing academic development". This was the opposite to case study 2 where the Lead CRN had completed a Master's degree and was exploring the possibility of starting a PhD. She was keen to develop her staff and had already "had a number of research nurses go and do the Masters in Clinical Research course". She had been supported by her R&D Director to establish a training facilitator post and after 3 years could appreciate the full benefit this provided to the workforce. It also enabled her to focus her attention on other strategic projects for ongoing development and support of the workforce.

Within case study 3 the Lead CRN was supported in her role a Head of Nursing (HON) who had an understanding of research. Education was very much part of the culture for the CRNs and seen as "very important" by the Lead CRN who "always tried to take everybody's training needs into account". Within case study 3 the Lead CRN confirmed that funding was limited due to "reductions"

and the trusts “financial position”. However, the CRNs were still encouraged “to seek out alternative sources of funding” to support their development.

In case study 4 the Lead CRN was studying for a PhD that was fully funded by the department and encouraged by the R&D Director, who was himself studying for a PhD. The positive attitude from management appears to have filtered down towards the CRNs who felt “very supported when it comes to education” and referred to being “encouraged” to carry our further study and “proactively look for courses”. The R&D Director was aware of the benefits of investing in his staff and was aware that “if you give them the opportunity and training, you build up a good culture*”.* He helped facilitate and support their studying by allowing them to adapt their working hours in order to allow sufficient time for study:

> *“I allow them to do four long days and one day off to do whatever they need. The ones that are doing extra degrees all do long days and one day off.”*

There was also a supportive attitude to providing study leave to attend courses; the general feeling was that leave would always be granted “provided the work is done”.

5.19.2. Culture

Educational structure

The academic profile of the four case studies was explored (see Table 5.19-3). However, the Lead CRNs in the larger organisations (Case study 3 and 4) were unable to describe what level of study their workforce had achieved. This was not the case in the other organisation which had a smaller workforce.

In case study 1 the Lead CRN was involved in training the clinical research network. She remarked that they “have a really robust education system” and was “one of the few areas that have an “Advanced research in Practice” course”. This was available for all CRNs within the network to attend annually and included role related training, professional updates and teaching. No other

case study had access to this type of programme. However, within the organisation due to funding restrictions there did not seem to be a strong focus towards professional development outside of mandatory training.

Table 5.19-3 Levels of education of CRNs in case studies

Case Study	Lead CRN Band	Lead CRN - Academic level	Size of CRN workforce	CRN training programme	Academic profile of CRN workforce
1	7	Nursing qualification	15	No	• 10 x RGN • 1 x BSc • 1 x MSc • 3 x NK
2	8b	MSc	120	Yes	Not known
3	8a	MSc	130	Yes	Not known
4	8a	MSc and doing PhD.	24	No	• 3 x PhDs (current) • 2 x MSc • 13 x BSc • 3 x RGN • 2 x Diploma

In case study 2, the Lead CRN felt that within her organisation there was a “good culture around education and training”. Within the CRF the staff were “positive and “always looking for opportunities to develop and promote professional development for staff”. With a larger workforce there had been more opportunity to develop an education structure. The Lead CRN had been able to develop a band 7 post specifically around supporting the education and training of the CRNs. This post holder was able to oversee the induction programme for new staff, which the Lead CRN saw as a “robust programme”. By linking in with external research structures, such as the UKCRF network, they had been able to “incorporate anything into their programme that was relevant and current”.

In case study 3 the Lead CRN was able to run a regular research forum that was open to all CRNs across the organisation. This included organisational and local updates. The trust also had a HON whose role was to embed evidence based practice within the clinical environment and develop clinical academic careers. She also helped support the Lead CRN and had seen a significant

benefit of this forum and referred to it as being “fantastic” and “phenomenal”. Having a senior identified individual that the CRNs could access to support their training and development was seen in a positive light. However, there was a sense that her role had “expanded” and that she could no longer “personally mentor everybody”. She was seen as someone that could “set up a structure of work streams across the trust” that was available for all clinical nurses.

The Lead CRN in case study 4 described the department as having “embedded education as part of routine assessment or management”. He also described how education was incorporated into the regular team meeting:

> *“we are quite proactive in that in every month in the meeting , as part of the agenda, is the study days and training that people are going to, how did it go and what did you learn? So a bit of reflection and sharing.”*

Management support

Personal attitudes to academic development also appeared to have an impact on the culture of education. In case study 2, the Lead CRN as mentioned above had completed a Master’s degree and had plans to commence a PhD. This appears to have given her the academic oversight to promote and support this level of education across her organisation. Her strong links with the senior nurses had enabled her to share her ideas and realise that “she needed to be pulled more into the organisation infrastructure to work with people to take this forward”. She was proactive in her plans to develop an education strategy and was keen to look for “opportunities” as to what she “could push and drive next”. The structure and level of her role appears to have given her the permission and authority to take her plans forward. Having been in her post for four years, the Lead CRN could now see “a complete sea change” in people’s attitudes to research and education. She could also see clear benefits for education of this cross working between research and the more clinical side of nursing now becoming apparent and confirmed that she got “a number of people getting in touch with me about going on a Masters Course and the research side of things”.

Within case study 3, the HON felt that the CRNs had very good educational support and this was due to a combination of “leadership” from the Lead CRN and the cross working with other senior nurses such as herself. Although the HON had a trust-wide remit, the Lead CRN had been able to link in with her to gain educational support for her team and also raise awareness around research.

External Influences

Funding for courses was an issue within all four case studies and all Lead CRNs had experienced a reduction in the amount of financial support available to them for training. In case study 3 the Lead CRN had a positive attitude to education which she saw as “important” but also a “real challenge”. A reduction in funding had impacted the amount of internal funding available and funding for academic courses was only available from external sources. By developing her informal links with the HON for Research and Midwifery, the Lead CRN had enabled her CRNs to have a greater awareness around the external training and funding available from places such as the NIHR for Masters Fellowships.

5.19.3. Summary of key findings: Education challenge

Quality of Leadership

- Attitude of senior leaders and the Lead CRN was linked with the degree of focus on educational support and academic development.
- There appeared to be a link between the academic profile of the Lead CRN and the degree to which they focused on academic development for their staff.

Culture

- A positive culture towards education helped to ensure the development of a robust education system.
- Personal attitude of the Lead CRN to academic development had an impact on the culture of education within the CRN team.
- External influences also impacted upon the educational culture.

5.20. Challenge 4: Politics

Table 5.20-1 Definition of the politics challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Political	Negotiating the politics of change associated with implanting and sustaining the improvement process, including securing stakeholder buy in and engagement, dealing with conflict and opposition, building change relationships and agreeing and committing to a common agenda for improvement.	Negotiating the politics of change associated with implanting and sustaining the CRN workforce, including securing stakeholder buy in and engagement, dealing with conflict and opposition, building change relationships and agreeing on a common agenda to ensure high quality research governance, support the achievement of NIHR objectives and ensure ongoing patient safety.

Questions were asked in an attempt to gauge the 'politics' of an organisation and what impact this had on research. Individuals were asked about the interaction of research and non-research teams and whether the CRNs felt empowered within their role.

Three key themes emerged in relation to the structure of the CRN workforce and the politics of the organisation. These were:

- Integration
- Change
- Leadership

Each of these three key themes had a number of sub themes as shown in Table 5.20-2

Table 5.20-2 Themes & subthemes for challenge 4 – "politics"

Theme	Sub theme
Integration of research within an organisation	• Facilitate • Conflict • Control
Reluctance to change	• Historical models
Senior Leadership within an organisation	• Stability • Empowerment

5.20.1. Integration of research within an organisation

Facilitate

There was a sense that at times efforts to facilitate the integration of research within an organisation were lacking; research activity was seen to "come below" clinical activity. Research teams were not prioritised when considering office space and were sometimes "geographically dispersed" across a site which was seen as reflecting on their lack of "importance". In some areas the ward or clinic manager would impose barriers which would prevent the integration of research. Efforts to carry out research related training were refused and although CRNs were not prevented from carrying out their role, in some areas there was no effort to support them or enquire about research.

CRNs remarked on the lack of interest towards research from clinical staff with comments such as "they're very nice when you go up there but interest (in research) nothing".

It was easier to facilitate integration if the CRN had worked in the area as a clinical nurse prior to moving into research. In this situation they felt "one of them" and were able to help the nurses out with clinical tasks. The CRNs felt they got "a better response from them" as they were "available" to help out and do a "bit of back scratching". This helped to build up relationships (as discussed further in the emotional challenge).

Other CRNs based themselves within their clinical area in order to help facilitate their integration. This allowed them to assist their clinical colleagues when the workload increased. One CRN remarked that in these situations "you've got to weigh up whether caring for people at the time is going to be more beneficial to staff". However, the CRNs knew that ultimately they would benefit from this when recruiting patients:

> *"the more time we spend in the department helping it becomes more of an advantage because people will then think, they are*

brilliant those research nurses and I'm going to ring them because I've got this amazing patient for them".

The wearing of a uniform also facilitated the integration of CRNs with their clinical colleagues. As discussed within the culture theme, uniform was very important for professional identity and patient perspective. However, it was also felt to impact on how they were received by their clinical colleagues. Where as many CRNs wore a specific colour for their role, some had chosen to wear the same uniform as their department. One team based within an emergency department wore the "team colour". They felt that if they wore the CRN uniform they "would alienate our team because we would be in a different colour".

When the organisation had a dynamic Lead CRN who was well networked with senior managers within R&D and nursing, efforts to integrate were more diverse and successful. In case study 2 the CRNs spoke of their efforts to integrate with the clinical nurses. This included invites to spend time in their team as well as newsletters and posters in the clinical environment. The CRNs were aware that research was "on the top of the agenda for the trust" and "it's part of what the Chief Executive wants". There was a political awareness that research was supported across the organisation and it was acceptable to promote it and raise its profile.

Conflict

Many articulated the sense of "conflict" that was sometimes felt between research and the clinical service. Some organisations had implemented joint roles where a nurse divided their time across the clinical and research requirements of a specific area. The aim of this was to support an "awareness and understanding of research" and "help train clinically based nurses". However, this often led to "conflict between the demands of each area". One Lead CRN (case study 4) cited a recent example where it was felt that developing a joint role had not worked. A chemotherapy CRN post had been developed which was divided across research and delivering chemotherapy as part of the clinical team. The aim of the post had been to be a "champion for

research" and to train other nurses "how to handle research patients on an ongoing basis". The Lead CRN reported that "how they divide their time becomes a problem". This leads to conflicting demands on the individual as explained:

> *"e-mails turn up that have deadlines and they won't be available. They will not be in the research area when the data comes, and that becomes a problem to the extent that it almost becomes too stressful for the person to perform the task."*

In this example the post had eventually been withdrawn because "it wasn't working".

There was often an "expectation" that if CRNs became an "integral" part of the team they should be "more flexible". This would entail helping out more clinically especially if "the study is a bit quiet". However, this may ultimately lead to research losing if CRNs are not focused on patient recruitment.

Funding of CRNs was also another cause of potential conflict especially when considering potential integration. Funding provided by the NIHR for CRN posts gives an expectation that these post holders will work solely on NIHR research. However, as cited by one R&D Director this poses the dilemma that although the aim "is to arrive at a situation where research is just normal business, it clearly isn't". He also felt that conflict within integration was also caused by what uniform the CRNs wore. He remarked that "it is very difficult to make research everybody's business if at the same time you identify special nurses and give them different colour dresses" to wear.

Some remarked on the conflict felt by senior nurses between their "professional obligations and managerial obligations". They knew that their "number one priority is to deliver a service". The R&D Director in case study one confirmed this saying "they would say they are very supportive of research and would support people doing research but in brackets they would say as long as have managed to do all the other things first, close brackets".

Control

At times control, or loss of control, was cited as one of the political challenges between the R&D department and others. In case study 2 the recently reorganised CRN structure had a Research Matron that came under the remit of the Lead CRN but also supported the trust-appointed CRNs within the directorates. Tensions had at times developed when appointing new CRNs due to the involvement of R&D; the Clinical Directorates felt that they had lost some control over the posts. A researcher within this organisation also talked about his attempts to maintain “control”. He confirmed that due to not always receiving the support he wanted “the best way to move forward is to have my own team and my own funding”. His CRNs were appointed within the trust model but he maintained control by providing the funding, either directly or indirectly.

Some organisations had looked at the possibility of clinical nurses supporting research and developing joint research/clinical roles. However, there was a fear from some senior managers that they would want to “keep control of their senior nurses” to prevent their team being “muddied up with the research team”. From an R&D perspective it was also viewed as potentially negative. One R&D Director expressed that this would be “a negative move”. He felt that if the CRNs were more integrated into the clinical service they would be “hijacked to do different things” and R&D would “lose control as the CRNs would spend their whole time seeing clinical patients”. Within case study 3 the PI referred to the “danger” of integrating CRNs and the “fear that suddenly research nurses will be pulled to support service gaps”. Within case study 2, the PI felt strongly that CRNs need to be a “separate team” as “when you mix clinical activity and research activity, clinical activity will always take over”.

5.20.2. Reluctance to change

Historical models

Much of the structure behind the CRN workforce appears to be linked to a historical evolution in response to the external environment and funding available. As discussed, across all organisations visited, regardless of size, the

structure for cancer research CRNs was a standalone team that had been in place for many years. This could be traced back to the set-up of the national research network system which had begun in 2001 with the set-up of the National Cancer Research Network (NCRN). In case study 2, which was a large acute teaching trust, the cancer CRNs were a standalone team but also appointed via the university and working in the trust on honorary contracts. This was a double challenge because of the complex nature of managing a team that were not substantively employed by the organisation. Work had started between the trust and the university to review these posts with the long term aim of making CRNs trust employees. However, this was seen as potentially "quite contentious". The Lead CRN had an awareness of the political sensitivities of her actions and so had proceeded with caution:

> *"it's very political, very tense, and I think they feel it's a big takeover bid so it's got to be very carefully managed which is why we are being quite careful about how we do this."*

There was an awareness that change could "destabilise" the team. The aim was to bring them under the trust system of being under Research Matrons as the benefit of this had already been realised. The Lead CRN confirmed that "I know that in terms of effectiveness and performance management we get much better outcomes through the CRF and the trust Matron".

5.20.3. Senior leadership within an organisation

Stability

The senior leadership within an organisation had an impact on the degree of awareness around research and this appeared to influence the experience of CRNs within the clinical environment. In one of the smaller case studies (case study 1), there had not been a substantive Chief Executive for 3 years leading but a series of interim post holders; consequently, there had been a lack of consistency around the Director of Nursing post. When talking to the CRNs they spoke of a lack of awareness and engagement from many of the clinical staff.

Some spoke of clinical staff having “zero interest in research” and research “being low on their priority list”. The R&D Director also commented:

> *“this has been a challenge for research because it drops even further. It drops even further because if you make any traction, you make a little bit of progress and then go away and every time you have to go back to go and you never collect £200, you just have to keep going back to go and start again. So it’s been one step forward, one step back”.*

Within case study 4 the Chief Nurse was new to the organisation. The previous post holder had been very supportive and aware of the benefits of developing a Lead CRN role. However, this had not been implemented before her departure and so discussions regarding this were due to recommence with the R&D Director taking the lead.

Within case study 2 the Lead CRNs links with the Chief Nurse had helped raise awareness around research across many of the senior nurses. Her role reported directly to a nurse director who then reported to the Chief Nurse. She was able to meet with the Chief Nurse twice a year to provide updates. The Lead CRN explained a positive impact of this had been that “all nurse directors know that if anybody’s talking about appointing a research nurse they need to get in touch with me and it’s our Chief Nurse that drives that”.

Empowerment

Effective senior leadership and sufficient seniority in the role appeared to support individuals being empowered and proactive to bring in change and develop autonomy in their role. As already explained, the Lead CRN in case study 2 was at a band 8b level and received ongoing and regular support from her R&D Director and one of the Nurse Directors. This appears to have empowered her to initiate changes that she could see would benefit the CRN workforce and ultimately the research portfolio. She was able to work with her senior managers in order to carry out initiatives to support the development of

the CRN workforce and articulate the benefits of much of the recent work she had done.

In contrast across the remaining case studies, two of the Leads CRNs were at band 8a level and one was a band 7. Within their roles they seemed less proactive about initiating actions that would bring about change. The band 7 Lead CRN spoke about feeling “frustrated” in her role and not “autonomous enough” and with limited “authority”. This may have left her less empowered to bring about change. However, she was within a much smaller organisation that was currently in special measures. Within case study 4 the Lead CRN only officially covered cancer with an informal remit for the trust CRNs. However, he was aware he had “no mandate” for the general CRN workforce and so did not feel it was his role to implement any trust wide strategies to benefit the CRN workforce.

Setting up an effective structure for the CRN workforce with trust based research matrons appears to have helped them feel more “empowered” within their teams and helped them to feel they had a “voice”. Within case study 2, the CRNs based within the Directorate attended a structured regular meeting that provided them with an opportunity to raise issues and concerns which could then be managed or escalated up to the Lead CRN. Across all case studies, some type of regular meeting took place within the research teams where current and future research studies were discussed and “where everybody can share ideas”. CRNs felt that they were “listened to” and were able to be involved in the setting of “realistic” recruitment targets.

5.20.4. Summary of key findings: Politics Challenge:

Integration:

- Research activity was not always a top priority but this could be enhanced when CRNs were better integrated into the area or were already known to the clinical area.
- Conflict develops between research and the clinical environment due to different priorities.

- There was a concern that by integrating clinical and research workloads some control may be lost if one aspect had more priority over the other.

Change:

- Some CRN workforce structures are linked to historical models that evolved due to the external environment. Although these may no longer suit the current environment, care is need if change is going to be implemented.

Leadership:

- Senior leadership within an organisation can impact the degree of awareness around research.
- Effective senior leadership and allocation of seniority to the role of Lead CRN enabled the individual to be more empowered and proactive.

5.21. Challenge 5: Emotions

Table 5.21-1 Definition of the emotions challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Emotions	Energising, mobilising and inspiring staff and other stakeholders who want to join in the improvement effort by their own volition and sustain its momentum through individual and collective motivation, enthusiasm and movement.	Energising, mobilising and inspiring staff and other stakeholders to be involved in processes to ensure high quality research governance and patient safety.

Questions within the emotional challenge focused around exploring the reality of running research studies within a clinical environment, the reception from clinical colleagues and any difficulties encountered. Themes within this challenge were less apparent than some previous themes. However, two key themes did emerge in relation to the emotional factors shaping the status of research and CRNs within the four case study organisations. These included:

- Engagement
- Recruitment

Each of these two key themes had a number of sub themes as shown in Table 5.21-2.

Table 5.21-2 Themes and subthemes of challenge 5, “Emotions”.

Theme	Sub Theme
Engagement with research	• Relationships • Buy in
Recruitment	• Emotional energy

5.21.1. Engagement with research

Relationships

There was a strong theme around the importance of relationships across all case studies; some participants likened this to a sense of "family". This was also linked to having a sense of "mutual benefit" between the CRNs and those within the clinical area where they recruited their patients. CRNs felt they were able to "develop a working relationship" which helped them to become accepted "as a colleague" and this worked both ways. It was also felt to be important if recruitment into the study was going to go well as the CRNs would get more support from clinical colleagues:

> *"you spend such a long time in there and it's helpful to be building up those sorts of relationships because they will ring you and say oh there's a patient"*
>
> — **CRN – Case study 3**

> *"I think the clinical nurses are more likely to do something, go the extra mile, if they've had something back"*
>
> — **Lead CRN – Case study 3**

However, the building and maintaining of relationships was for some an ongoing process depending on where their study recruitment was based. CRNs were aware that "when a new study starts you are always trying to build up those relationships again". They referred to relationships being "strong" and "supportive of each other" but that once a study closes "you leave because you go on to another project. So it doesn't disappear necessarily but you have to build it up again if you ever go back into that area". CRNs often expressed a sense of loss and regret that they were leaving an area they had become settled in. Others were able to benefit from longer term studies where they were in an area for a prolonged amount of time and so could really cement their relationships and this benefitted the study. The CRNs felt that this benefitted the study as "some of the long term studies are easier to do because people understand why you are there".

The flexibility of research nurses within the clinical areas was also important as they were then seen in a positive light and so this helped towards building the relationship. It was felt that there was some “give and take” and that overall they got “a better response from them if also available to them” and so “if you’ve got a quiet minute and they need a bit of help, you build up relationships”. The PI’s could also see the importance of relationships when engaging with patients for research:

> *“we are all to do with relationships. You can’t treat us like pawns in a chess game. The whole thing about informed consent is that the patient has to trust the person who is taking consent and that’s all about human relationships.”*
>
> — **Principal Investigator – Case study 1**

Another PI could also see the impact of relationships between the CRNs and patients and referred to it as a “meeting of equals as you are asking the patient for a favour”. He felt that this equality of interaction was more productive as it moved away from the “patriarchal relationship” that is found within a conventional clinic.

Buy in

A busy clinical environment and competing priorities meant that often the “buy in” or general commitment was at times low. CRNs were aware that clinical colleagues had “101 other things going on” and “it's just so low down on their priority list they don’t even get to grips with the basics”.

There was awareness that everyone faced “challenges” but CRNs explained that at times they encountered “a lot of resistance on the floor” which in turn made their role more challenging. In case study 4 the Lead CRN explained that the CRNs had “to fight for everything, if you’re asking for space, time or whatever” and in that scenario “you have to get extra emotional energy to make that request because the relationship is not a good one”.

5.21.2. Recruitment

Emotional Energy

The workload behind organising patient visits was often seen to require a lot of emotional energy. The CRNs spoke of the implications of a lack of dedicated space. Time was spent planning and organising patient visit appointments and this often required them to book a clinical room. However, this did not necessarily guarantee that it would be available on the day and there was an awareness that they were "at the bottom of the pecking order when it comes to clinical space". One CRN explained:

> *"you might think you've booked a room, organised it, but you go over and they've given it to somebody else. You will be the first one they will knock on to give the room to somebody else. It's as if they say, oh that's only research. I've even had the room taken off me for a doctor to sit and do dictaphoning, which is very disheartening."*
>
> — **CRN – Case study 1**

Others also commented on the effort required to organise and see patients. Sometimes they were only able to access "quiet rooms which aren't clinical spaces". However this then required additional effort as the CRN "had to take them to phlebotomy to have their bloods done and take them to where the blood pressures machines are in clinic". All of this required a lot of "energy" and additional "effort".

The difficulties within the clinical environment impacted how the CRNs felt within that environment. Some spoke of "not belonging", being "stuck in a corner" or "pushed to one side" and that they "struggle every week". Due to these difficulties some reported that at times they would "take the patient off and find space elsewhere". Although this may not be in a clinical environment. In case study 2 one CRN commented she had decided to take firm action and so explained:

"I was running a study that was literally nearly everybody in the clinic that I could get in, and I basically got a piece of A4 and stuck it on the door and said this is for me"

— **CRN – Case study 2**

She was uncertain as to whether this was acceptable but explained that it had enabled her to spend the morning in clinic and recruit all eligible patients into her study.

5.21.3. Summary of key findings: Emotional challenge

Engagement with research:

- There was strong agreement concerning the importance of relationships. This was mainly related to the experience of CRNs within the clinical environment.
- A busy clinical environment meant that general commitment to research was at times low requiring additional effort by the CRNs in order to achieve a result.

Recruitment:

- CRNS' spoke of the large amount of effort that is often required in order to organise dedicated space for patient visits.

5.22. Challenge 6: Technology and Infrastructure

Table 5.22-1 Definition of the technology and infrastructure challenge as described in Table 3.4-1

Challenge	Original definition in framework	Definition applied to CRN workforce
Technology and Infrastructure	The design and use of a physical, informational and technological infrastructure that improves service quality and the experience of care.	The design and use of a physical, informational and technological infrastructure that improves research governance and the experience of patients who take part in research studies.

Questions focused around any recent technology developments which had occurred within research or across the organisation and - if relevant - how easy it had been to incorporate these into the research process. The overall infrastructure within which the work of CRNs took place was also discussed.

This was difficult to analyse as the data relating to this particular challenge was relatively sparse and so themes were not obvious to identify. However, those that did emerge are shown below:

Table 5.22-2 Themes and subthemes for the challenge: technology and infrastructure.

Challenge	Theme	Sub theme
Technology	Attitude	• Hindrance • Avoidance • Engagement
Infrastructure	Dedicated clinical space	• Room issues • Organising • Staff support

5.22.1. Attitude

Hindrance

From some participants there was a perception that IT changes were disruptive. This was more marked in the two smaller organisations (case study 1 and 4). Neither had a system of electronic patient notes but other IT changes that had occurred were viewed negatively. With case study 1 a new clinical portal had been introduced to manage all the pathology systems. However, comments

such as “terrible”, “abysmal” and “difficult” were made with an overall view that “the clinical portal doesn’t work very well” and “the organisation has taken a step back rather than a step forward as a consequence of its introduction”. Staff had also experienced problems with lack of compatibility from external data capture systems used within research studies (leading to delays in starting studies). These problems were seen as due to the use of old computer systems within the NHS. In case study 4 there was a collection of different IT systems; most participants viewed them as “more of a hindrance than a help”.

There was a general feeling across the 4 case study organisations that IT changes were problematic and caused “problems because research wasn’t considered”. In case study 3 a new IT system was under development but the CRNs remarked that “research wasn’t engaged with at all” and they “were a by-product”. There was acknowledgement that for success “there needs to be a centralised approach funded by the trust to R&D”, however CRNs felt that “research doesn’t seem to have been a priority in digitalising health records” and was seen as “more of a hindrance than anything else”.

Avoidance

At time, staff also appeared to actively avoid the use of new or emerging IT systems. In case study 1 the Lead CRN confirmed “I deliberately don’t use it, I leave it to the girls (CRNs)”. When asked, the R&D Director was unable to explain the clinical portal and expressed frustration towards it. Related to the introduction of electronic patient notes there was a feeling of relief that currently they were not implemented and the CRNs remarked “we are lucky in our poverty”.

There was also a feeling of avoidance by the organisation of trying to take research needs into account. Staff had arranged a meeting while new IT systems were under development but they were met with comments of “we can’t fit that in now” and “it’s a bit late”.

Engagement

However, the situation was very different in case study 2. Here they had just moved across to a system of electronic patient notes that had been met with engagement from the research teams and a positive approach. The Lead CRN remarked that “we engaged quite early on in the process around research and made sure it was included in the initial set up phase”. She attributed the success of research integrating the new IT system successfully to their “good links” and admitted that “three years ago we wouldn’t have got a look in, we’d have been shouting and shouting but it’s definitely changed”. She attributed this to being able to generally lay the foundations around research over the last 18 months so that when new initiatives come along, research is considered because links are already in place.

5.22.1. Dedicated Clinical space

Many of the CRNs worked within outpatient settings and finding dedicated space in which to see their patients was frequently highlighted as an issue. Individuals mentioned that they often felt they were “squatting”, “at the bottom of the pecking order” and “not a priority”.

Room issues

Issues with space were ongoing and in many cases had to be renegotiated with each clinic and on a “case by case basis”. CRNs mentioned difficulties such as that the clinical areas “try to fit us in where they physically can” and “there’s a priority order and you are at the bottom”. There was a strong sense of much time spent on “negotiation” by the CRNs when it came to identifying space in which to see research patients. This would often result in a room but often it was quite last minute and so CRNs had to “ring the day before” in order to get confirmation. Ultimately the research nurses would work where ever there was space and this resulted in a wide array of locations where research patients were seen:

"I have seen research patients in the cardiac catheterisation unit, in the day surgery unit, on the respiratory ward and in a clinic area".

— **CRN – Case Study 3**

Organising:

Difficulties in finding allocated clinical space meant that a lot of time was spent organising clinic visits:

"there's an awful lot of, you know like a swan, there's paddling going on underneath and I think a lot of effort goes on getting the kit moved around the hospital".

— **Principal Investigator – Case study 1**

"and so every time we go over there we come out of this environment and you have to drag everything with you".

— **CRN – Case study 1**

Staff support

It was often the case that allocating dedicated space for research was down to the support of the clinical staff who would "fit us into a room that's free for 5 minutes if at all possible" and "find an empty room if there is one". However, some CRNs did encounter a negative response when organising space to see research patients. In case study 1 the CRN remarked that staff would not actively prevent them from finding dedicated space but they were aware that the staff "don't want to do it" and that they (the CRNs) were always "the first one they will knock on to give the room to somebody else". Therefore this often left them with the uncertainty that they would be asked to be asked to move in the middle of a patient research appointment.

5.23. Summary of key findings: Technology and Infrastructure Challenge

Technology - Attitude

- I.T changes were often perceived as more of a hindrance than a help. Especially in smaller organisations. Research is not always considered by the organisation when I.T changes are planned.
- Staff were also known to avoid using new I.T systems if possible.
- In organisations with a good research infrastructure the implementation of I.T changes had been an easier process.

Infrastructure – Dedicated Clinical Space

- Finding dedicated space in which to see their patients was frequently highlighted as an issue
- CRNs often struggle to organise dedicated space as research was not viewed as a priority.
- Research appointments were often held in a variety of locations across the organisation.

5.24. Summary

This chapter has presented the results from both phases of this study. Chapter 6 will now discuss the results of each phase in order to explore the current structure of the CRN workforce and the experience of the CRNs who work within it.

Chapter 6: Discussion

6.1. Introduction

This thesis has presented the findings from a mixed methods study exploring the experience of CRNs within acute NHS trusts and the structure of that workforce. This chapter will consider the study findings and will discuss these in relation to the limited amount of evidence concerning CRN experience and workforce structure. The findings will be interpreted in order to inform the development of a 'model' organisational structure for CRNs working within acute hospital trusts. It will highlight the study's original contribution to knowledge and suggest implications for practice and future research. The strengths and limitations of this study will also be considered.

6.2. Summary of key findings and recommendations

The study has identified that the CRN workforce has evolved in a reactive and inconsistent manner shaped by internal and external influences. Within many organisations this has included the development of a Lead CRN post to oversee the workforce. This study has revealed the importance of this role not only in providing leadership and direction for the workforce but also as a link to the remainder of the nursing workforce as well as a conduit to increase awareness of research and the CRN role.

RECOMMENDATION:

Organisations should ensure that the CRN workforce is well led with the establishment of a Lead CRN post. This should be linked in with both the R&D Director and the senior nursing leadership team. It should be placed at a band 8 position within agenda for change but the exact level within this band will depend on the size of the CRN workforce and the responsibilities within the role. Consideration of the proposed CRN workforce model (see figure 6.8.1, pg 223) may assist practice and provide organisations with a suggested framework for structuring their CRN workforce and the aspects within this that a Lead CRN will need to implement.

STAKEHOLDER = R&D Department and senior nursing leadership team.

The current NHS climate means that the delivery of research is at times difficult and often overlooked as it is not perceived as a priority. This has an impact on the experience of CRNs within the clinical environment and the level of support and understanding from clinical nursing colleagues.

The CRN workforce appears to be isolated from their clinical nursing colleagues with possible fragmentation between Oncology research and the remaining clinical areas.

Research and the CRN role appears to be misunderstood by the remainder of the nursing workforce with lack of awareness in some areas.

RECOMMENDATION

Work should be undertaken to address the lack of understanding of research and the CRN role. This would in turn address the isolation of the CRN workforce within an organisation.

STAKEHOLDER = R&D Department and senior nursing leadership team.

Work to review and restructure the CRN workforce may not directly benefit an organisation in terms of increasing NIHR recruitment activity. However, benefits may be gained in demonstrating support and leadership for the CRN workforce as well as increasing awareness around research and the experience of the CRN workforce.

RECOMMENDATION

Review of the CRN workforce should be a decision taken by the R and D Department

STAKEHOLDER = R&D Department

6) The structure of the CRN workforce is being influenced by the emergence of non-nursing roles within the research team.

RECOMMENDATION

Further work is required in order to understand these roles and their ongoing development and integration within the overall research team.

STAKEHOLDER = R&D Department

6.3. Original contribution to knowledge

The literature review provided a small amount of information on the CRN workforce and its structure within a few organisations. This study reviewed this in greater detail and demonstrated the lack of consistency within the CRN workforce structures and the factors that impact on the experience of CRNs. It has demonstrated the reality of running research within a busy healthcare system comprised of what is often viewed as conflicting priorities.

This is the first study that has examined the CRN workforce and how organisations have structured their individual workforces. It has identified the importance of having a dedicated Lead CRN to support and lead a CRN workforce and the positive benefits this can bring. It is also the first study to examine NIHR recruitment in relation to the CRN workforce and the relationship between the two. These both have important implications for research delivery which will be discussed in this chapter.

The thesis concludes with a proposed CRN workforce model that aims to assist practice and provide organisations with a suggested framework for structuring

their CRN workforce and the aspects within this that a Lead CRN will need to implement.

6.4. Interpretation of findings

These will initially be discussed in relation to each of the study aims. A more general discussion will then be presented.

6.4.1. Study aims

To explore how the CRN workforce is currently organised within NHS Acute trusts

As reported in Chapter 3 there is little contemporary evidence as to how the CRN workforce is structured in trusts across England and Scotland. The three empirical papers examined gave an overview of the CRN workforce but did not report on how CRN roles had been structured within research or clinical teams. The three unpublished workforce reviews were presented in slightly more detail but again gave no insights as to any workforce structures. Findings from this study demonstrate that the NIHR has provided the infrastructure to form the essence of the architecture that underpins the CRN workforce. Within this 86% (73/85) confirmed that their CRN workforce works as part of one of the local Clinical Research Networks with additional structures such as CRF's, BRC's, and BRU's. Examination in more detail within the four detailed case studies revealed a lack of consistency within the CRN workforce structure; cancer remained a standalone team within each of them. Across three of the case studies the structure of the CRN workforce appears to have developed in a reactive manner influenced by both internal and external factors. Internal factors related to the size of the trust and engagement of clinicians whilst external factors largely related to the level of funding available. Case study 2 was the only organisation to have fully reviewed and re-structured their CRN workforce; this had resulted in good support both from R&D and the wider organisation. Case study 4 had carried out a smaller review of their workforce which had primarily involved changes within the two main teams (cancer and non-cancer)

regarding the banding of the CRNs so that the majority of posts were now a band 6. Other possible changes discussed within the review had been put on hold by a change of senior nursing leadership within the organisation.

The effectiveness of the CRN workforce structure appears to be influenced by strong nursing leadership. Within the questionnaire, 68% (76/111) of respondents were in a nursing role with the remaining 32% (35/111) in a non-nursing role. Within case study 1 the Lead CRN at band 7 level expressed isolation, a lack of autonomy and a lack of links with senior clinical nurses so preventing the integration of the workforce with the wider nursing workforce. There appeared to be a lack of acknowledgement from the Chief Nurses office of the need to develop links with the CRN workforce (the Lead CRN remarked that in the space of two years she had had "4 managers at Associated Director of Nursing" level). Although the R&D Director was aware of the deficiencies in the structure of her role he did not appear motivated to address them.

Of the 68% that were nurses (76/111), the length of time that their post had been established ranged from one to 20 years (mean = 47 months). In addition 66% of the roles had been established within the previous six years suggesting that the role is relatively new and so the impact may still be emerging within many of these organisations. Within the literature review, Ledger et al (2008) highlighted the need for a dedicated Lead CRN to oversee the workforce. Case study 2 demonstrated the impact of an established role which had become embedded within the organisation. The current post holder had held the post for four years but the overall duration may in part account for the successful integration of the CRN workforce.

Conversely the Lead CRN role at case study 2 was at a band 8b level which enabled the post holder to develop a robust leadership structure including strong links into the senior nursing and R&D infrastructure (as well as provision of a well-supported leadership structure for the CRN workforce). Her strong strategic perspective alongside her role autonomy and authority had enabled her to develop a well-supported CRN workforce that appeared embedded within

the wider nursing workforce; this had enabled an increasing awareness and understanding of research to be developed within the organisation.

The impact of this robust leadership structure was evident in several respects. Projects were underway or being planned to integrate research and raise understanding. These included: appointing research champions within clinical areas; the set-up of a dedicated post to support and deliver training programmes around research and professional development, and the integration of research matrons with clinical matrons to support the out of hours clinical cover service. The Lead CRN referred to putting out a “tentacle into what’s normal, clinical infrastructure” in order to facilitate raising awareness and integration; this appears to have been effective with positive outcomes becoming increasingly evident.

The two remaining case studies had a Lead CRN role at 8a level but exhibited a mixed picture. Case study 3 had a poor structure for reporting and accountability but the Lead CRN was linked in with the Senior Nurses forum. However, she had no support with clinical decisions and so felt professionally isolated. Within case study 4 the remit of the Lead CRN role remained within oncology with no formal responsibility for the trust wide CRN workforce. This meant a lack of overall leadership for the CRN workforce; although research was embedded within cancer, there was less awareness across the organisation with research seemingly “hidden”. Although the Lead CRN had developed strong links with the R&D Director there was no formal links with the Chief Nurses office although there had been a recent change in post holder so plans were in place to initiate these.

Overall the study identified the importance of the Lead CRN role in providing support for the CRN workforce. Despite the reported lack of senior oversight for some of the post holders, the presence of an identified lead for research had a positive impact across all of the case studies. An ability to “draw things together” and “open doors” have been highlighted as some of the positive benefits for the CRNs. Post holders highlighted the visibility of research across the organisation and although some did struggle to achieve effective links, the

mere act of striving to establish a link helped to support an increase in awareness of the workforce.

Study findings indicate that the structure of the CRN workforce is being influenced by the emergence of non-nursing roles within the research team. The pilot survey identified an additional fifteen roles that were involved in supporting delivery of research. Within the main survey an additional twenty-nine roles were identified. There may be a degree of crossover of responsibilities in these roles but with over half of organisations (n = 55/95, 59%) confirming they have Data Managers within their teams and almost three quarters (n = 65/93, 70%) having Clinical Trial Co-ordinators, this does show clear evidence that the structure of the whole research workforce is changing and evolving; this will undoubtedly impact the CRN workforce. Currently this development is viewed with some scepticism by CRNs especially within smaller organisations. Although there appeared no difference in these roles between the reviewed and un-reviewed organisations, there was a difference between the large and smaller organisations. The concern expressed by the CRNs in Case study 1 on the introduction of a non-nursing role may indicate the uncertainty initially felt by CRNs around this change. Despite the fact that posts such as Data Managers will release CRNs from the burden of inputting study related data into databases - a non-clinical activity not traditionally associated with nursing - some nurses expressed feelings of ownership and appeared quite territorial towards this activity. Even in Case study 3 where more of the nurses had worked with non-clinical roles, some CRNs expressed that they were “struggling” and “finding their feet” when working alongside these roles. CRNs were aware that non-nursing roles are appointed at pay bands lower than themselves but in many cases cover a large amount of the activities that they do. They had an awareness of the significance of research funding and the continual drive from R&D to recruit more participants into studies. Therefore, some of their trepidation towards these roles may be related to a personal feeling of a growing threat towards their own role.

The presence of a stand-alone CRN team for cancer research across all four organisations appears to have caused a degree of hostility and competition.

Across all sites this could be traced back to the setup of the National Cancer Research Network which appears to have now resulted in a section of the CRN workforce being isolated and separate from the remainder of the workforce. The survey identified that cancer studies are run in the majority of organisations (n=88/95, 92.5%) and only 7/95 respondents indicated that this was not the case. If the case study findings were to be replicated across the country then the CRN workforce may be slightly fragmented in its overall structure. Focus groups held in case study 2 and 4 included a CRN working within cancer. Within case study 2, where they were appointed through the university, the individual had not met any of the other CRNs before. She confirmed that the team was "managed on its own" and worked "very much within their own clinical area".

Therefore in summary, the overall picture exhibits a workforce comprised of an inconsistent structure but primarily divided between cancer and non-cancer. The Lead CRN is a developing role to take oversight of the CRN workforce but may not yet been developed within many organisations. More recently the workforce has seen the development of non-nursing roles which are viewed with uncertainty. This may well prove to be the catalyst for changes within the CRN workforce itself.

To explore and compare the experience of CRNs within different organisations

This study identified that the experience of CRNs within different organisations is multi-factorial. It is mainly influenced from within their organisation but where external factors are impacting across their organisation this was found to also shape experiences.

The theme of isolation is consistent with findings of previous studies. However, it is generally not the individual CRNs that feel isolated but the workforce that feels isolated from their clinical colleagues; there was a sense that they belong to each other but not to the organisation. This appears to be related to the feeling that they are not linked in with the wider workforce and are "hidden" from their clinical colleagues. Some of the Lead CRNs expressed this in greater

detail as they could see the result of not having formal links with the senior nursing structure across their organisation. For case study 4 this only applied to links outside of oncology but for case study 1 and 3 it applied across the organisation. Within the literature review isolation was linked to a lack of understanding around the CRN role; this was a theme across the whole study. The questionnaire found that only 27.5% had confirmed that they thought the CRN role was understood. This was further explained in the case studies by the CRNs who revealed a range of reasons which included that they were perceived as having a “cushy role” which meant they were not a “proper nurse” and viewed as being “data collectors”. The CRNs felt they were perceived as a threat by their clinical colleagues; this was exacerbated when patients contacted the CRNs first when a problem developed as they felt the CRNs had the time, leaving the clinical nurses feeling side-lined. This also appears to be related to another factor: the CRN experience is impacted by the current pressures within the NHS. Within the questionnaire and across all case studies there were numerous references to “competing priorities”, “conflict” and “lack of time”. This was especially evident in the two smaller case studies (1 and 4) which were both in special measures and had been for the previous two years. Research staff were aware that research was viewed as “bringing something extra that’s not required” and low on the priority list. Whilst CRNs did think that clinical nurses could see the benefits of research they felt they viewed it as an additional task that could be left undone when facing an ever increasing clinical workload. This was not consistent with the findings of studies discussed within the literature review and may indicate changes in the healthcare system within which NHS staff currently work. However, until research is viewed as business as usual it will always be seen as an additional extra that can be dropped when the workload pressure increases.

Further consistency between themes within the literature review findings and this study included feelings of lack of support and understanding by the CRNs. The literature review identified that CRNs often felt unsupported by clinical colleagues with occasional hostility. Spilsbury et al (2007) had termed this “consent but not co-operation” and this quite accurately articulates the themes which initially came out in the pilot survey and then across the main survey and

which strongly influenced the experience of CRNs within the clinical environment. The pilot survey had initially reported that the reality of the day to day importance of research differed to the perception and opinion of its overall importance. Within the main survey almost three quarters of respondents (n = 72/102, 70.5%) agreed that research was considered important and relevant across the organisation but only a quarter (n = 27/102, 26.5%) agreed that staff within the clinical environment felt the same. Comments confirming the link with Spilsbury et al's theme include that "staff will tell you that research is important to the organisation but they are not always willing to co-operate" and that it is "mentioned in strategy documents but has a low overall priority". The interviews and focus groups illustrated the challenges faced by CRNs working in the clinical environment including difficulties faced in identifying dedicated space for research and the lengths they often had to go to in order to identify a room to see their research patients. Overall they were aware that staff may recognise that research is important but with an ever increasing workload at times they find it hard to support.

Spilsbury et al (2007) reported on the strategies that CRNs had developed in order to overcome difficulties with their clinical colleagues, including helping out in ward areas and involving themselves in clinical care. This was borne out within the case studies where CRNs discussed the strategies, referred to as "favours and bribes" that they had developed in order to integrate better with their clinical colleagues and increase awareness of research. Many CRNs realised the benefit they could bring to the clinical areas by taking on aspects of patient care which helped to open up lines of dialogue and get the clinical nurses "onside". Those CRNs working within clinical teams had realised that by expressing their gratitude to clinical colleagues who helped identify a patient, ensured an ongoing relationship so possibly ensuring future support of their research; this also helped to raise the understanding around the research process and give clarity around the CRN role.

The literature review highlighted the mechanisms for the establishment of CRN roles within organisations and identified the different employment routes and the large number of CRNs that had no nursing line management in place. Within

this study, the survey explored who currently line manages the CRNs and found that in a large number of organisations (n=73/89, 82%) there is CRN involvement in the line management of the workforce. However, the survey also identified a small number of organisations (n=9/89, 10%) where no nursing line management, either research based or clinical, is in place. This was further explored in the case studies and found to be an emotive subject that some CRNs had very strong feelings about. Although all four case studies did have examples of CRN involvement in the line management of the workforce, some of the workforce in case study 3 were not line managed by a CRN despite there being a Lead CRN in post. Here some CRNs were managed by more senior clinical nurses which at times left them feeling “isolated” and separate from the remainder of the organisation. This link between poor line management set up and isolation was also identified by MacArthur et al (2006) and discussed in the literature review. The interviews and focus groups enabled this to be explored in a greater depth revealing that for some CRNs knowledge and understanding of research from a line manager was more important than an understanding of the clinical side of their role, whereas others favoured being line managed by clinical nurses as their lack of knowledge concerning research meant that the CRNs were “left alone” and “could do what they want”. Across the four case studies there was a range of line management arrangements in place which demonstrates that there is not currently ‘one size that fits all’.

The literature review highlighted the poor support that was available for the training and development of CRNs. This issue was explored across both phases of this study and revealed that support has greatly increased over the last decade (certainly since the three workforce reviews were undertaken). The aspects of education explored were initial induction programmes, ongoing training and support for academic development. Within the survey there was overall support for initial training from the majority of respondents, a point illustrated by high levels of attendance at induction programmes by CRNs. The more mixed picture regarding ongoing training revealed that some respondents felt that CRNs were not a priority whilst others thought CRNs had more opportunities. Some of this was related to the type of organisation (especially evident in the more positive answers given by those from a teaching trust).

However, regardless of organisation type, many of the respondents were unable to describe the full academic profile of the CRN workforce; this was especially true for larger organisations. Within the case studies the Lead CRN and their personal attitude to academic development appeared to influence their approach to the overall academic support of their workforce. The lower banded Lead CRN within Case study 1 focused more on professional development (as compared to academic development). The remaining case studies - with a band 8a or 8b at the helm - had more of a focus towards academic development, a point that appears to be related to their own academic achievements. Overall the picture across the 4 case studies is inconsistent and appears strongly related to internal influences. At times the support appears fragmented; within the larger organisations it is more difficult for the Lead CRN to completely oversee the full training programme. This had been partly resolved within case study 2 with the introduction of a CRN training facilitator post who was able to provide dedicated support to the induction and training programmes offered to CRNs.

The data was further explored for what Farmer et al (2006) had termed “additional categories of silence” and two further themes emerged related to the experience of CRNs. The first of these is the importance of relationships which emerged as a strong theme within all the case studies with the occasional mention in some of the survey open comments. This theme appeared to relate to various aspects of the CRN role including clinical colleagues and patients. Across all four focus groups CRNs spoke of the importance of building and maintaining relationships, their transient nature if they left an area at the end of a study and the benefit of remaining in one area for a prolonged amount of time. Lead CRNs referred to the positive impact relationships could have on recruitment into studies and also when developing links with senior colleagues. One of the Principal Investigators saw it as crucial to all aspects of the research and concluded that “we are all to do with relationships”.

The second emerging theme was the importance of uniforms to CRNs and especially how these related to professional identity; not only how they perceive themselves as a nurse but their thoughts on how others perceive them. This

emerged in Case study 1 and so was explored throughout the remaining case study visits. CRNs spoke with passion about the importance they attributed to their uniform and there was strong agreement that it was linked to making them "feel" like nurses and ensuring they were "embedded in the nurse culture". They felt that patients related to them better with a greater amount of respect and allowed them to present a more professional image. Colour was important with many advocating dark blue as this was linked with a more senior role (as traditionally it is the colour worn by ward sisters across the NHS). Colour was also viewed as important by those who wore a dedicated colour and so valued the increase in awareness they felt it gave them.

However, not only was there a lack of consistency across case studies related to uniform, in the larger case studies (2 and 3) there was a lack of consistency across the CRN workforce as to what was worn. Within case study 3 the options included a dedicated uniform, the departmental uniform or one worn by nurse specialists. Within case study 2 the CRNs appointed by the university wore no uniform due to a lack of funding; this resulted in consternation and frustration for this particular team.

In summary, themes identified within the literature review of isolation, lack of support and understanding, line management and role set up, and training and development have continued throughout this study although at times the detail has altered. Isolation remains but is now more associated with the workforce and not individual post holders. However, the role remains misunderstood despite a large increase in the workforce. A significant influence on multiple aspects of the CRN experience relates to the current environment of a busy NHS within which the workforce is based. This appears to be hindering the integration of research with clinical care.

What is the experience of other senior research staff concerning the CRN workforce?

The literature review revealed that this is not an aspect that has previously been studied. This research question was therefore included to gain an oversight of

how the CRN workforce is viewed but an in-depth description was not anticipated as it formed a short part of the overall interview. An insight into how other senior research staff view the CRN workforce was obtained from the case study interviews undertaken with the PIs and R&D Directors. Senior research staff across all case studies spoke highly of the reputation of the CRN workforce; much of this was related to the efficiency of how research studies were run. The PIs interviewed had been involved in research for between nine to 20 years. They had all experienced the changes that had occurred from having a dedicated CRN workforce with overall leadership from a Lead CRN. Comments included that the service is now “seamless”, “works really well” and they now “have everything in place”. However, although they could see the benefit of the Lead CRN role, regarding the workforce it was really only the benefits of having CRNs working within their clinical area that they could fully appreciate. They had all worked with the historical model of CRNs (when nurses were appointed by the Consultant and very often line managed by them) which pre-dates the establishment of the NIHR. As a result they all now appreciated the dedicated support that the CRNs received and seemed relieved to no longer have to involve themselves in directly managing them. There was a feeling that the CRNs within their area were better supported by the Lead CRN and that “having someone with experience makes a big difference”. They could also see the patient related benefits and commented that they “get positive feedback from patients” and that “the patients love coming up and being in studies”.

The PIs had firm ideas as to how the CRNs should be structured within the clinical service. Many of them expressed their reluctance to fully embed their CRNs within the clinical nursing team preferring them to remain as “a separate team”. They expressed concerns that “when you mix clinical and research activity, clinical activities always take over” and “in the current climate it would be a negative move to fully embed them as it would take them away from research”. They also discussed the clinical skills that they preferred the CRNs to have. Many of them could see the benefit of the CRN working in the relevant clinical area prior to moving into a research role. Comments of “she’s a fantastic example of a research nurse because she came from the clinic” and “she used

to be a clinical nurse so has a good rapport with the team" demonstrate the benefit this brings. However, there was also an appreciation of the downside of this as they were aware the CRNs then feel "more of a pressure to help out if they are short on the ground".

The interviews with the R&D Directors (in case study 1 and 4) revealed very different attitudes to the CRN workforce, despite them both being within the smaller organisations. Within case study 1 there was more of a hands off approach with the R&D Director seeming to leave support of the workforce to the Lead CRN and only receiving updates when they met. He was not aware of details such as how the CRNs were received in the clinical environment and had no involvement in education as he felt he could leave the Lead CRN "to provide the education that she felt they need in order to fulfil their roles". In contrast with this, the R&D Director in Case study 4 took an active interest in the CRN workforce. He explained that when he started in post he made a "strict rule that the research nurses work for R&D and not the Consultants". He had led the review of the CRN workforce and favoured a trust-wide Lead CRN. However, as this required involvement of the Chief Nurses office and there had been a change in post holder, he had set up an interim arrangement of the Cancer Lead CRN providing informal support to the CRNs across the organisation. He was critical of the clinical matrons and the support he felt they should give to CRNs as "in an ideal world clinical matrons should have research as part of their role but we don't live in an ideal world and our matrons just don't have time to care". He was very supportive of the educational support for CRNs and would always try to fund any requests for academic support that he received.

In summary, the CRN workforce appears to be highly respected by senior staff working within research. The P.I's can see the benefit of the dedicated support provided by the Lead CRN and the positive impact this has had on running research studies. They prefer their CRNs to remain in a role that is dedicated to research but can see the benefits of working in the clinical area first in order to gain the relevant clinical skills. The view of the R&D Directors differed greatly although only 2 such interviews were undertaken.

To examine the effect of re-organising the CRN workforce on NIHR targets.

As discussed in the background chapter the NIHR high level objectives include to “increase the number of participants recruited into NIHR Portfolio studies” and to “increase the proportion of studies in the NIHR portfolio” (NIHR 2015). In this study, the effect of reviewing did not make a difference to the number of interventional or observational studies or recruitment into observational studies. However, it was found to have a statistically significant effect on recruitment into interventional studies. As might be expected, larger Trusts and those with more CRNs in the workforce did have more studies in progress and more patients recruited. However, when just the fifteen organisations who had carried out a full review were examined they did appear to have increased the number of their interventional and observational studies over a period of five years.

6.5. General discussion

This study has presented an overview of the reality of research within the NHS. It has identified some key areas concerning the pressures within the NHS which impact on research leading to a lack of priority, which is associated with the isolation of the CRN workforce and the lack of understanding around the CRN role. This illustrates that the influences on research are multi-factorial and so need to be globally addressed within an organisation. Within the “Organising for Quality framework” the authors’ state that, related to quality improvement, the six common challenges identified are “problems which any organisation will need to find solutions that will work for them, and if they do not do so will ultimately lead to disappointment and failure” (Bate et al 2008:167). In the same way for research, this study has identified that these challenges apply to the success of the research arena within an organisation and so therefore all need to be addressed. The authors also state that within the framework, leadership was not given its own category as “it is not a challenge that can be separated from the other challenges but is integral to them all” (pg 175). This re-enforces the key role of the Lead CRN in supporting the integration of research within their organisation.

The success of research relies on being able to develop a process that allows it to infiltrate within the organisation to enable it to become normal practice. So the culture of the organisation needs to allow research to permeate through within all levels until it becomes business as usual. Within the “Organising for Quality framework” culture involves a shared mind set or ethos. This involves recognition and acknowledgement from the top so that all levels of staff understand its importance. Within the literature review, it was identified that Spilsbury et al (2007:553) had coined the phrase “consent but not co-operation” and this was confirmed within this study. A strong research culture is imperative to overcome this and integral to this is the Lead CRN role. Development of effective links and engagement with key stake holders such as R&D and the Chief Nurses office will serve as a channel to allow the flow of research awareness and understanding across an organisation.

Associated with gaining engagement from key stakeholders may involve the politics of conflict and opposition in order to agree a common agenda. Again this is a further component of the Lead CRN role and in part illustrates the rationale for ensuring that the post is structured at a senior level to ensure both the experience of the individual and the required authority.

One of the issues identified within this study is that currently research is not seen as a priority within the NHS and this impacts how the CRN workforce is perceived. Despite the Health and Social care act (2012) making research a core function of the NHS , research is often over looked especially as internal and external factors further increase the pressure felt by clinical staff.

One of the factors identified within this study which has great significance for the success of research delivery across the NHS is the issue of isolation. Initially identified in the literature review related to how CRNs felt within their role, this theme has been further confirmed within this study but presented slightly differently. Within this study isolation has been identified as being associated with the CRN workforce as a whole. CRNs mainly work within research teams and so feel supported by their colleagues. However, the picture outside of this is very different and the workforce appears to be isolated from its

nursing colleagues. However, the stipulations within the NIHR funding model necessitate a total focus by the CRNs on patient recruitment to ensure delivery of NIHR objectives. This reduces the opportunity to develop working links with clinically based nurses.

If this issue of isolation can be overcome, the workforce becomes more visible so increasing the awareness of the clinical research agenda. At present it appears that for many organisations research is yet to be fully integrated into their ethos and culture. People need to feel that research is relevant to their role and not an added extra or additional burden as the healthcare environment of the NHS is too busy for altruism. The CRN workforce has the potential to be the mechanism that can be used to support developing research awareness and knowledge to embed a pro-active research culture within an organisation. The questionnaire identified thirty-nine clinical areas where CRNs are running studies so demonstrating the breadth of research exposure that the workforce can bring.

In considering the success of research to be linked with the six 'Organising for Quality' challenges used within this study, aspects of culture and education are inextricably linked. A change in research culture needs to infiltrate all aspects. The CRN workforce primarily supports the medical model for research supporting the development of new treatments. However, they are ideally placed to facilitate research across their own profession and support nursing colleagues to advance the agenda of nursing research. This sharing of skills will impact on how nurses view the relevance of research to their own role and career. Within education CRNs have the potential to support the advancement of clinical academic careers.

A recent guidance document on clinical academic careers provides organisations with advice on how to support its development (AUKUH 2016). It refers to identifying existing resources within an organisation including R&D. The phase 1 questionnaire in this study identified that 81% (73/90) of respondents stated that their CRN workforce are employed through R&D so providing a mechanism to sanction this approach. In highlighting the lack of

research awareness across many organisations, this study has identified that currently the CRN workforce is a lost asset in helping to drive the research agenda forward. Support of clinical academic careers within an education environment may well be the vehicle which will launch the integration of the CRN workforce and increase the understanding concerning their role. Figure 6.5-1 illustrates the impact of this; increasing research awareness and support of clinical academic careers could lead to an increase in nursing research with a greater number of experienced nurse researchers who have the potential to develop their own research and studies which can become future NIHR portfolio studies:

Figure 6.5-1 The research trajectory

The proposed trajectory above forms the beginning of a potential pathway which could be further developed to help support a change in culture, a shared mind set and a move towards research no longer being seen as lacking priority.

Research Nurses may not all wish to pursue a clinical academic pathway for themselves. However, working within a clinical research environment will have provided them with valuable transferrable skills which include an understanding of research governance requirements, in-depth knowledge of the informed consent process and its importance, and practical experience of collecting and recording research data. The integration of the research nurse workforce with their clinical nursing colleagues would help to ensure a sharing of knowledge and understanding concerning the set up and delivery of research within a busy healthcare environment, so helping to address gaps in knowledge across this wider nursing workforce. Those in the early stages of directing their nursing career towards a clinical / academic focus would have an accessible source of support and knowledge from fellow colleagues within their own profession. This

can only be of benefit to the wider research arena and so support the development of a pro – active research culture which works towards helping to diminish some of the earlier highlighted difficulties such as a lack of integration and a feeling by some that research is irrelevant within a busy healthcare environment. This can help to develop the CRN workforce from its current standing as a possible lost asset to one that helps support both the wider research agenda and the development of clinical academic careers within the profession.

6.6. Strengths of the study

A major strength of this study was the mixed methods design. This enabled the researcher to carry out a thorough examination of the data in response to the research questions.

The national survey (and excellent response rate) has provided a broad understanding of the CRN workforce and the structures within it; prior to this there was no national data available which provided an overview of how organisations structure and support their CRN workforce.

The case studies have provided in-depth descriptions related to the reality of enabling and supporting research within a busy healthcare system. This will provide organisations such as the NIHR with a comprehensive insider understanding of running research studies directly from the workforce at the heart of this effort. It will also highlight the importance of understanding the reality of how healthcare systems and research interact in order to inform future strategy. Without a mixed methods approach a full understanding would not have been gained because use of a single method would not have provided the in-depth understanding which this study has revealed.

Prior to this study there was no examination of NIHR recruitment activity related to CRN workforce size. As the role of a CRN is focused on supporting the successful delivery of research studies, this study provides an important overview of the impact this can have. By examining the CRN workforce within

the different types of acute trusts, this study had demonstrated the important role that acute teaching trusts have in supporting NIHR recruitment.

A further strength was my role as researcher. As an experienced CRN with in excess of 20 years in the role, I have lived through first-hand the development of both the role and research infrastructure within which it is based. As a Lead CRN within my own organisation I had direct contact with the main phase 1 study participants. I was therefore able to directly engage with this group in order to raise awareness of the survey. Therefore, for many, when the survey arrived they were already aware of the study and the importance the results would have. This may also have contributed to the very high survey response rate of 77% that was achieved.

6.7. Limitations of the study

This is the first study which has aimed to examine the national CRN workforce and develop recommendations from the findings. However, the survey findings only present an overview from a single perspective as the questions were asked to the Lead CRN on behalf of the CRN workforce. In small organisations this would have been easier to articulate as CRN numbers are lower and so their experience of the issues being examined may have been more consistent. However, in larger organisations, and as articulated within the responses, the experience of some of the CRNs differed greatly across the various research teams and clinical areas. Although this is a finding in itself, it may also reduce the generalisations that can be made from the overall results of the study. A more comprehensive approach would be to conduct a national survey that directly approached CRNs within all acute trusts.

Four case studies were examined within phase 2 of this study. In determining selection criteria the researcher aimed to examine a small and large organisation within both reviewed and non-reviewed organisations. Case studies were selected on the criteria described in chapter 4. For case study 1, 2 and 3 this was unproblematic and the initially selected site agreed to take part. However, the selection of Case study 4 proved more difficult. There was no

response from the initial invite despite a confirmation in their survey response that they were willing to take part. The second site approached had no Lead CRN as the post holder who had completed the survey had recently left the organisation. Therefore case study 4 was selected but this was not quite as well matched a case to case study 1 as the CRN workforce was slightly larger (25 nurses as opposed to 15) and the NIHR recruitment total for 2014/2015 was slightly larger (6685 participants compared to 1006 participants). When case study 4 was visited it transpired that the Lead CRN did not have a formal remit for the trust- wide CRN workforce; this had not been apparent within the survey responses.

It was planned to interview the R&D Director at each of the 4 case studies. However, this was only achieved in case studies 1 and 4. Despite multiple attempts by the Lead CRN in case study 2, it proved not possible to arrange an interview. Therefore an interview was held with the R&D Manager. Although this included discussion of some relevant points the interview content did not appear as rich as those directly obtained from the desired individual within case studies 1 and 4. Within case study 3 the R&D Director post was vacant and efforts were being made to appoint a new post holder. The Lead CRN had initially arranged for the researcher to speak with the Deputy Director of R&D. However, on the day of data collection, the interview was cancelled and it proved not possible to rearrange. An interview was instead carried out with the Head of Research for Nursing and Midwifery.

In planning this study it was hoped that the 2 reviewed organisations would be able to provide a report of their review and recommendations in a similar format to those unpublished reviews that had been obtained at the commencement of this work. However, the review in case study 2 had taken place over 10 years ago and in case study 4 there was not one available. Therefore the additional information that had been anticipated to provide a greater insight to the rationale and process of the review was not available.

The study included a look into the impact of changes within the information technology (IT) systems on the process of running research studies. This had

been seen by the researcher as relevant due to a recent national report regarding implementation of a system across the NHS of electronic patient records. The government had previously published a document laying this out with the objective of developing an IT system which can “present the entirety of a care pathway as a single virtual electronic record (DOH 2012, pg 9). The researcher had seen the beginning of the implementation of this within their own organisation and the difficulties it had caused to researchers and CRNs in the running of studies. It was therefore hoped to gauge a national picture of this and the problems being experienced. However, the study found that in reality many organisations were not yet at the stage of implementing such a system and so it was not possible to gauge the impact on research studies. As time has now passed since the data collection phase of this study it is anticipated that if the organisations were contacted now more information related to organisation wide IT changes would likely be available.

The quality and detail of information received from Trusts also varied greatly. The information relied on the knowledge and experience of the research lead responding. Further analysis of respondents’ shows that 68% (76/111) were identified as a Lead CRN and of these 21.5% (23/107) had been in post 21 months or less. Whilst this does not suggest a lack of knowledge, it may in some instances limit the detailed insight of the respondent regarding the development of the workforce over time.

6.7.1. Implications for the national CRN workforce

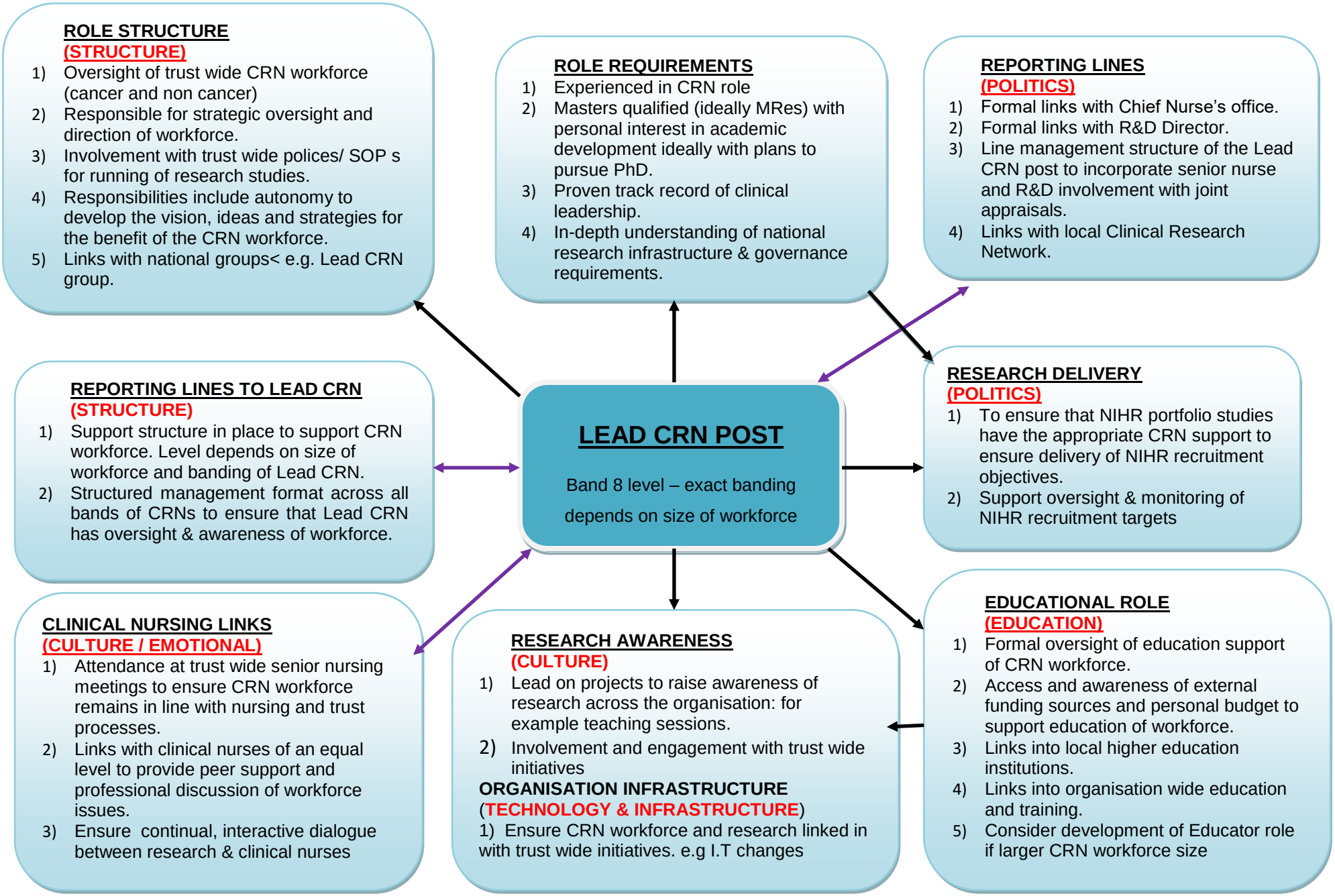
This study has offered a valuable insight into a growing workforce within the nursing profession and the reality of running research studies within a busy healthcare environment. It has demonstrated that where the workforce is well supported with formal links into stakeholders such as R&D and the Chief Nurses office, there is a positive impact which appears to facilitate a greater understanding and awareness of research. On the basis of the study findings a recommended model (see Figure 6.7-1) is proposed that will allow an organisation to put in place a structure that will provide oversight and support of

the CRN workforce and help to create a research culture that will raise the profile and understanding across all clinical areas.

The study has identified the importance and value of an identified and senior research nurse who has oversight and responsibility of the CRN workforce. Central to this model and a specific recommendation from this study is the importance of a Lead CRN role to take oversight and responsibility of the CRN workforce and its role to ensure delivery of NIHR objectives and the research agenda of the organisation. Attention should also be paid to the banding level of this post as this study has given an insight into the importance of ensuring that the Lead CRN has the authority and autonomy to influence the CRN workforce and make recommendations for its development. Findings would suggest that this post should be placed within the band 8 bracket of the Agenda for Change structure. This is important as within the clinical nursing structure, posts at this level are often a Matron or Lead Nurse with oversight of a clinical service; it is important that within research there is an equivalent structure to ensure parity.

When considering the role requirements it is important to ensure that the Lead CRN in experienced within the arena of research and clinical trials and has an understanding of the national research infrastructure and governance requirements. Other aspects of their experience should include previous oversight of research teams which would have facilitated the development of their management and leadership skills. An interest in academic development and a personal drive to progress their studies up to PhD level will ensure an informed oversight of the educational responsibilities within this role. Funding to support further academic study is limited and bodies such as Health Education England are seeing a reduction in the amount of funding they can provide. An acknowledgement that this may impact on the financial support available to a Lead CRN is required. However, previous experience of the Lead CRN should enable post holders to provide robust support for the educational component of their role.

Figure 6.7-1 (Over page) Recommended CRN Workforce model


ROLE STRUCTURE
(STRUCTURE)
1) Oversight of trust wide CRN workforce (cancer and non cancer)
2) Responsible for strategic oversight and direction of workforce.
3) Involvement with trust wide polices/ SOP s for running of research studies.
4) Responsibilities include autonomy to develop the vision, ideas and strategies for the benefit of the CRN workforce.
5) Links with national groups< e.g. Lead CRN group.
ROLE REQUIREMENTS
1) Experienced in CRN role
2) Masters qualified (ideally MRes) with personal interest in academic development ideally with plans to pursue PhD.
3) Proven track record of clinical leadership.
4) In-depth understanding of national research infrastructure & governance requirements.
REPORTING LINES
(POLITICS)
1) Formal links with Chief Nurse's office.
2) Formal links with R&D Director.
3) Line management structure of the Lead CRN post to incorporate senior nurse and R&D involvement with joint appraisals.
4) Links with local Clinical Research Network.
REPORTING LINES TO LEAD CRN
(STRUCTURE)
1) Support structure in place to support CRN workforce. Level depends on size of workforce and banding of Lead CRN.
2) Structured management format across all bands of CRNs to ensure that Lead CRN has oversight & awareness of workforce.
LEAD CRN POST
Band 8 level – exact banding depends on size of workforce
RESEARCH DELIVERY
(POLITICS)
1) To ensure that NIHR portfolio studies have the appropriate CRN support to ensure delivery of NIHR recruitment objectives.
2) Support oversight & monitoring of NIHR recruitment targets
CLINICAL NURSING LINKS
(CULTURE / EMOTIONAL)
1) Attendance at trust wide senior nursing meetings to ensure CRN workforce remains in line with nursing and trust processes.
2) Links with clinical nurses of an equal level to provide peer support and professional discussion of workforce issues.
3) Ensure continual, interactive dialogue between research & clinical nurses
RESEARCH AWARENESS
(CULTURE)
1) Lead on projects to raise awareness of research across the organisation: for example teaching sessions.
2) Involvement and engagement with trust wide initiatives
ORGANISATION INFRASTRUCTURE
(TECHNOLOGY & INFRASTRUCTURE)
1) Ensure CRN workforce and research linked in with trust wide initiatives. e.g I.T changes
EDUCATIONAL ROLE
(EDUCATION)
1) Formal oversight of education support of CRN workforce.
2) Access and awareness of external funding sources and personal budget to support education of workforce.
3) Links into local higher education institutions.
4) Links into organisation wide education and training.
5) Consider development of Educator role if larger CRN workforce size

Responsibilities within this role are multi-factorial and, if structured appropriately, will ensure a well-supported workforce and the successful delivery of research. The role needs to incorporate leadership, influence, autonomy, research delivery and a passage way into associated areas such as clinical nursing, R&D and the senior nurse infrastructure. In case study 2 the Lead CRN referred to ‘tentacles’ into the normal clinical infrastructure in order to facilitate integration. The Lead CRN must be able to understand the set-up of nursing across the organisation in order to ensure that the presence of research within clinical areas occurs in a seamless fashion; any difficulties can then be identified early and quickly resolved. The suggested model includes two-way arrows for reporting lines and clinical nursing links. Just as important as communication spreading out from research is ensuring the feedback and inclusion of research with developments and updates across the organisation. Therefore the Lead CRN must ensure integration with peer colleagues and seniors to ensure inclusion with organisational priorities and updates regarding the national healthcare agendas. This may include awareness of national healthcare regulators such as the Care Quality Commission and national nursing updates such as the recent changes with the Nursing and Midwifery council (NMC) revalidation. The flow of information is also important between the Lead CRN and the workforce. The size will dictate the exact structure of how the teams and leadership roles are structured. However, the lead CRN must ensure links into this to ensure her own awareness and oversight of the entire CRN workforce.

In summary, this model suggests the development of a structure facilitated by a central leadership role which will act as the conduit to both the CRN workforce and the wider nursing and R&D arena whilst ensuring a two-way direction of flow for communication, education and oversight. Implications for research delivery

This study highlighted that clinical nurses “lack insight into the true nature of the CRN role” with resulting confusion and lack of understanding. It is imperative that CRNs increase their visibility and spend more time in the clinical environment. The increase in non-nursing roles provides CRNs with an

opportunity to delegate much of their non-clinical activities to these post holders in order to concentrate more on patient centred activities. This will facilitate a greater presence within the clinical environment so further raising awareness of research and the CRN role.

This study examined whether restructuring would have a positive impact on patient recruitment and portfolio size; this was not demonstrated in the statistical analysis. A closer inspection of those organisations that had restructured revealed that there was great variation in the amount of restructuring undertaken with some only making minimal changes to banding or allocation of staff. Of the 59 Trusts who had undertaken some form of restructuring, 25% (15/59) confirmed that a comprehensive restructuring had taken place. From these there was a positive increase in interventional and observational studies within a six year time period. However, the size of the CRN workforce is only known for the year 2014/15 making meaningful comparison unreliable as CRN numbers are known to be linked to recruitment of patients. Given the importance of Trust size and CRN workforce numbers any future study will need to ensure this data is captured for the periods being compared. Variations in the degree of trust restructuring are also an important potential confounding factor and clear criteria should be used when making future comparisons in performance.

6.7.2. Recommendations for further research

This is the first study to examine the national CRN workforce and to explore first-hand the experience of CRNs and their role in supporting clinical research within a busy healthcare system. Previous studies have reported on local CRN workforces but no study has attempted to describe the national workforce. A future study which approached more than one individual within the R&D department to obtain the information or was able to carry out interviews with the identified individual may elicit more in-depth data. In addition 23% (n = 33/111) organisations did not complete the survey and all organisations in Wales and Northern Ireland were not approached. For a full UK picture these omissions should be rectified.

The study identified an emerging non-nursing workforce within research. This appears to be comprised of numerous roles although - due to the reactive nature of their development - there will undoubtedly be some cross over in their responsibilities. This workforce will have a large impact on the set up and responsibilities of the CRN role and workforce going forward; a national study to review its size and remit is indicated in order to further progress the running of research studies within the NHS.

A case study design has been used within four organisations which comprised a medium, large and two teaching trusts. It would also be of interest and relevance to explore the CRN workforce within small and specialist trusts and more generally in a larger number of each of the five trust types. Now that a suitable and relevant framework has been established for data collection the case study component of this study could be repeated in a larger number of organisations to gain a more in-depth analysis of structure and CRN experience.

6.8. Personal reflection

Planning and conducting of this study provided me with the opportunity to carry out an extended piece of work within an area that I have based my career. I have seen the development of the CRN role, the growth in the workforce and experienced the opportunity to develop within a clinical and academic environment so acquiring skills and experience within this field. Therefore this study provided me with the opportunity to use these skills and in-depth knowledge to personally explore how the national CRN workforce has evolved following a decade of increased funding from the NIHR and an increase in research governance requirements. Through my current role, as Lead CRN in a large teaching trust, and previous roles I have seen and been involved in some examples of growth and development within organisations. However, it was a privilege to have the opportunity to personally explore and gain oversight of the national picture.

My in-depth knowledge of the area and being part of the workforce I was due to study, gave me easy access to my target population and so to commence my initial survey. My successful 77% response rate was, I am sure, in part due to my pre-existing involvement with the workforce I was studying. I had been able to raise awareness of my planned work with some of my intended respondents in the months prior to the survey being circulated. However, at the commencement of my survey planning I still had a large number of organisations where I needed to either identify the Lead CRN or other post holder responsible for the CRN workforce. Therefore, many respondents did not have prior knowledge of the survey prior to my initial contact with them.

Within phase 2 of this study I was reliant on the support of the Lead CRN at each organisation to help organise the required interviews and focus groups. I am therefore immensely grateful for their support and assistance with the planning of my visits to their organisation and am well aware that the success of this phase of the study was in part due to their support. The organisations to be studied were based on pre-defined criteria. Once identified it was apparent that I had previously met 2 of the 4 Lead CRNs. However, although this may have influenced their decision to support the study there was no difference in my experience at each of the sites on the day of data collection.

Overall, my experience in clinical research and my current role meant that I was ideally placed and skilled to carry out this study. The end result has provided an initial overview of the CRN workforce alongside first hand personal accounts from those in a CRN role. Moving forward this work can provide the foundations for ongoing studies which can provide further insight into clinical research and the associated workforce.

6.9. Summary

This chapter has aimed to interpret the findings of this study. It has identified the importance of the Lead CRN to oversee the CRN workforce. A workforce model has been presented as a way to ensure a well-supported and integrated CRN workforce which will enable an increased understanding and awareness of research. The strength and limitations have been reviewed together with some recommendations for practice and possible future research areas have been suggested. The concluding chapter will provide some final reflections on the future of research and the CRN workforce.

Chapter 7: Conclusion

7.1. Overview of findings

As this study has progressed, it has examined various aspects of the CRN role and workforce to provide both a national overview and local case studies. Operating within a busy and pressurised healthcare system the workforce and the research agenda which it aims to promote and deliver on is isolated and currently lacks priority and wider understanding.

There is a dearth of literature relating to the structure, effectiveness and experience of the CRN workforce in the UK. This thesis has attempted to address this gap in knowledge by undertaking a mixed methods study utilizing a survey of CRN workforces across England and a detailed case study of 4 Trusts. It has used NIHR data in an attempt to understand the impact of conducting a CRN workforce review on the number of studies run and recruitment.

The wide variation in the structure of the CRN workforce and its leadership has provided insight into both high performing and sub-optimal structures. This insight has allowed an exemplar CRN workforce model to be developed, providing a template for Trusts to work towards.

Key findings from the study suggest that effective leadership and a pro-research culture are at the heart of successful CRN teams. Effective leaders need sufficient seniority to effect change, influence senior management and provide a credible presence at grass roots. These leaders must be role models, demonstrating effective behaviors and with appropriate academic preparation to support a developing workforce.

7.2. Research agenda moving forward

Overall, the implications of this study are two-fold. They have highlighted some important findings regarding the structure of the CRN workforce and the experience of the CRNs within it and this has facilitated some recommendations. However, of equal importance are the implications of this

study to the research agenda moving forward. Development of well-structured CRN teams led by a strong leader with structured links into key stakeholders that enables integration, understanding and a progressive research culture is vital if some of the contemporary difficulties identified within this study are to be addressed. This will help support the integration of the CRN workforce and raise the profile of the research agenda, so supporting ongoing evidence based patient care and treatments.

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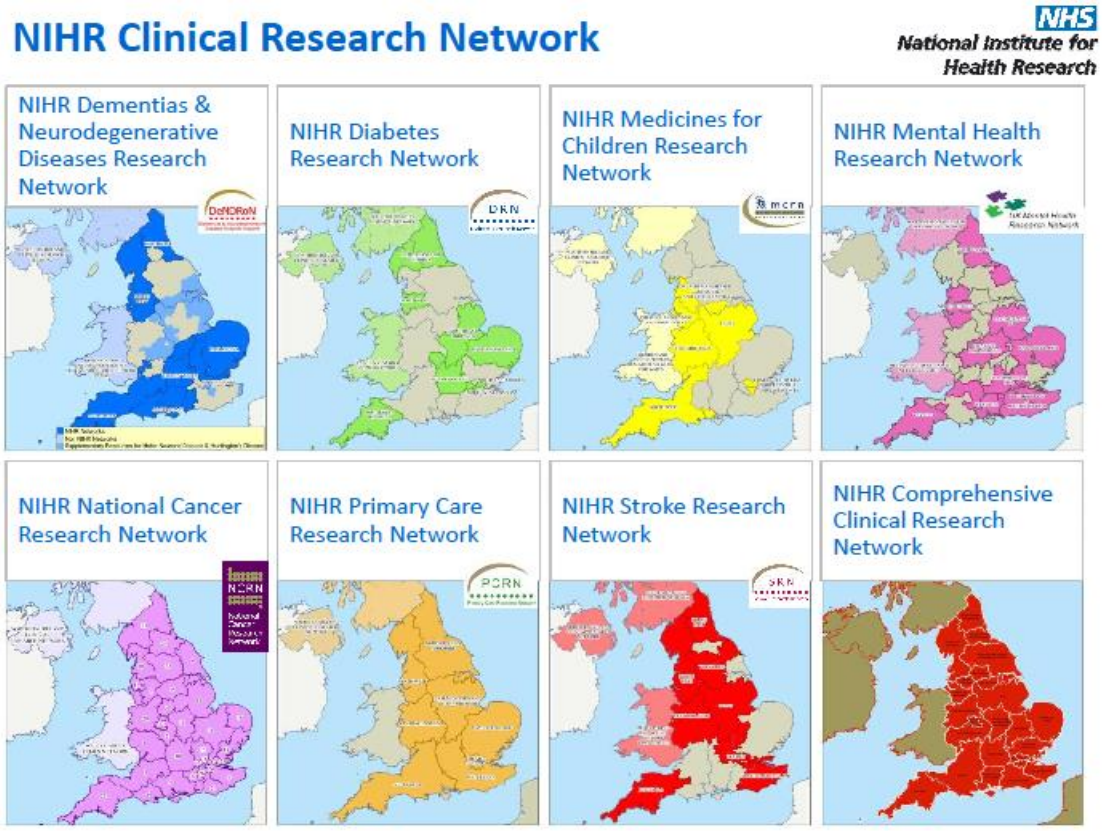
Appendix 1. NIHR Clinical Research Networks – 2006 to 2014



Appendix 2. NIHR Divisions and Clinical Specialities

NIHR Clinical Research Network – Divisions and Clinical specialities

- Division 1
  - Cancer
- Division 2
  - Cardiovascular Disease
  - Diabetes
  - Metabolic and Endocrine Disorders
  - Renal disorders
  - Stroke
- Division 3
  - Children
  - Genetics
  - Haematology
  - Reproductive Health and Childbirth
- Division 4
  - Dementias and Neurodegeneration
  - Mental Health
  - Neurological disorders
- Division 5
  - Ageing
  - Dermatology
  - Health services and delivery research
  - Oral Health and Dentistry
  - Musculoskeletal disorders
  - Primary care
  - Public Health
- Division 6
  - Anaesthesia
  - Peri operative Medicine and pain management
  - Critical Care
  - Ear, Nose and Throat
  - Gastroenterology
  - Hepatology
  - Infectious Diseases and microbiology
  - Injuries and emergency
  - Ophthalmology
  - Respiratory Disorders
  - Surgery

Appendix 3. Literature search strategy

Search strategy

Aim of review – to identify empirical research relating to Clinical Research Nurse (CRN) experience and the organisation of the CRN workforce in the NHS.

Sub questions

1. What is the experience of CRNs within their role?
2. What is the experience of other research staff concerning the CRN workforce

Inclusion criteria:

1. Primary research studies
2. Studies published from the year the database started. Due to the uncertainty of when the first reviews were completed this will ensure that no articles are missed.
3. Articles relating to the UK CRN workforce only due to different healthcare systems and research infrastructure
4. Published in English peer reviewed journals

Search terms

Nurse	Workforce
Research Nurse	Research Nurse workforce
Clinical Research Nurse	Research Nursing workforce
Clinical Research Nursing	Research Nurse Team
Research Nurse Practitioner	Research Nursing Team
Trials Nurse	Nurse workforce
	Nursing structure

Appendix 4. Eligibility form

Eligibility form

Author	
Title of paper	
Journal	
Year, volume, issue & page	
Is the paper about the UK CRN workforce? Yes / No	
Is the paper relevant to the research question and worthy of further consideration?	
Relevance	Is the paper about the experience of CRNs within their role? a) Yes b) If no – reason for exclusion: - Not about CRN experience. - Not in the English language
	How does the paper answer the research question? a) Does it explore the experience of CRNs within their role? b) Does it explore the experience of other research staff concerning the CRN workforce?
Include / Exclude	
Additional Comments	

Appendix 5. Data extraction form

Data extraction form

Author, year and paper title	
Stated aim of study	
Methodology used	
Year of study	
Characteristics of study sample:	
Data collection methods	
Data analysis methods	
If workforce review , numbers identified:	
Key findings:	
Main reported conclusions	
Any additional issues identified within the study:	

Appendix 6. Critical Appraisal Skills Programme (CASP) analysis

CASP analysis

Paper	Was there a clear Statement of the aims of the research?	Is a qualitative methodology appropriate?	Was the research design appropriate to address the aims of the research?	Was the recruitment strategy appropriate to the aims of the research?	Was the data collected in a way that addressed the research issue?	Has the relationship between the researcher & participants been adequately considered?	Have ethical issues been taken into consideration ?	Was the data analysis sufficiently rigorous?	Is there a clear statement of findings?	How valuable is the research?	Number of questions given a yes response put of 10.
Coulson, C & Grange, A (2012). Developing clinical research nurses.	Yes	Yes	Yes	Not discussed	Yes	Not discussed	Not discussed				? not relevant to CASP analysis as mixed methods
MacArthur, J & Hill, G (2006). Professional issues associated with the role of the research nurse.	Yes	Article covers 2 studies – mixed methods. Study 2 used focus groups	Yes	Yes	Yes	Not discussed	Not discussed	Not discussed	Yes	Yes	6 ? not relevant to CASP analysis as mixed methods
Spilsbury et al (2008) The role & potential contribution of CRNs to clinical trials.	Yes	Yes	Yes	Yes	Yes	Not discussed	Yes	Yes	Yes	Yes	9
MacArthur, J, Hill G & Callister, D (2014). Professional issues associated with the clinical research nurse role.	Yes	Mixed methods study (online survey to CRNs in Scotland)	Yes	Yes	Yes	Not discussed	Applied for but deemed not required by Ethics Committee.	Yes	Yes	Yes	8 ? not relevant to CASP analysis as mixed methods

Appendix 7. Review of papers examining the UK Clinical Research Nurse

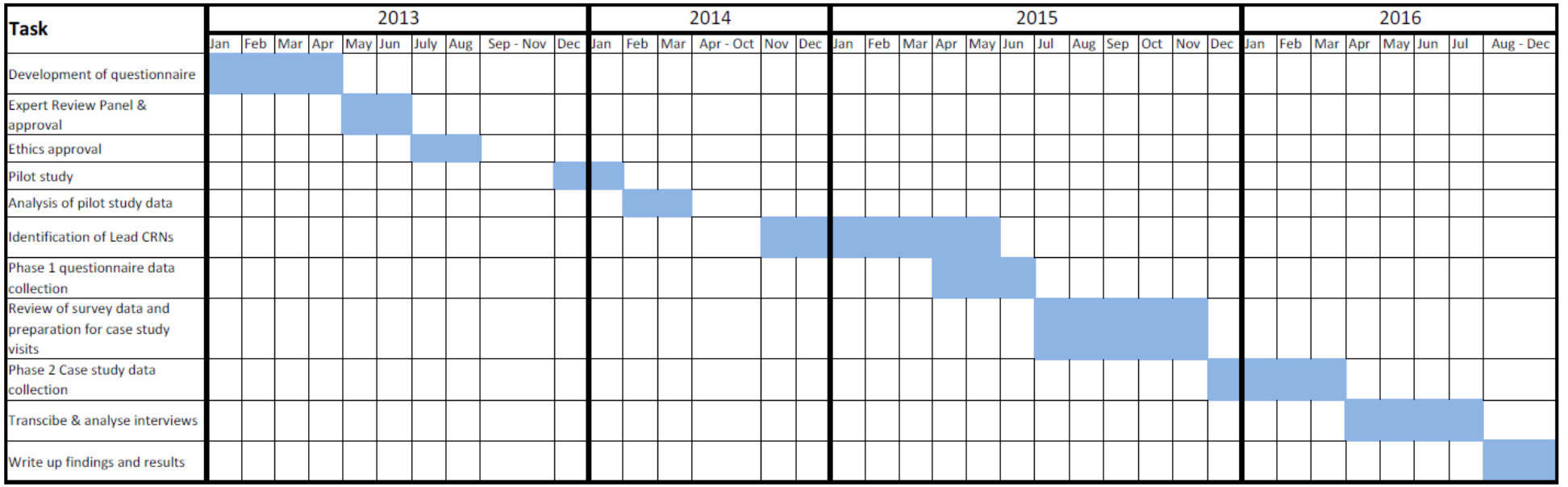
Author	Paper Title	Journal, Year, volume, issue and page	Empirical research or anecdotal?	Focus of paper? - CRN experience - Workforce structure - Role responsibilities - Patient care - Other	How does the paper answer the research question?		Impact factor	Additional comments
					Does it explore the experience of CRNs within their role?	Does it explore the experience of other research staff concerning the CRN workforce?		
A Campbell, T	Patient focused care: Primary responsibilities of research nurses	British Journal of Nursing, 1998. Vol 7	Anecdotal	Patient care	No	No	0.53	Focuses more generically on patient focused care.
Handscomb, K and Phillips, H	The Clinical Research Nurse	Cancer Nursing Practice (2004) 3 (6) pg 6 – 9.	Anecdotal	Describes educational course developed for clinical research nurses.	No	No		Describes development of a course by a senior Oncology research nurse.
Choo, J, Blundell, S & McGinnis, E	Ethical issues & challenges in pressure area research – The research nurses perspective.	Journal of Tissue Viability, Vol 21, pg 105 - 108	Anecdotal	Looks at ethical issues of working as a research nurse in pressure area research	No		1.129	
Gibbs, G and Lowton, K	The role of the clinical research nurse	Nursing Standard, Vol 26, No 27, pg 37 – 40.	Anecdotal	Role responsibilities, challenges and future.	No		0.08	Paper describes development & components of the CRN role
Pick, A, Liu, A, Drew , V & McCaul, J	The role of the research nurse	Nursing Times, 2011, Vol 107,	Anecdotal	Role responsibilities	No		0.12	Narrative account of what the role involves.
Hemingway, B and Storey, C	Role of the clinical research nurse in tissue viability	Nursing Standard, 2013, Vol 27, no 24	Anecdotal	Article explores the experiences of 2 nurses who were appointed to a job share position as CRNs.	Not related to research question.		0.08	Discusses challenges and strategies involved in adapting to the CRN role.
Coulson, S and Phelan, L	Clinical research in paediatric oncology & the role of the research nurse in the UK.	European Journal of Oncology Nursing, 2000, Vol 4, no 3, pg 154 - 161	Anecdotal	Gives an account of aspects related to clinical trials.	No		1.618	Discusses role responsibilities of the research nurse.
Coulson, C and Grange, A	Developing clinical research nurses	Nursing Times, Vol 108, no 22	Empirical research.	Study aimed to identify issues faced by CRNs. Used questionnaire surveys, focus groups and interviews.	No		0.12	Article explores authors reflections on the development of the research nurse role.
Arrigo, C, Gall, H, Delogne, A & Molin, C	The involvement of nurses in clinical trials	Cancer Nursing, 1994,	Survey	Overview of survey that was sent to 312 nurses in 15 European countries to document the involvement of nurses in clin trials.	No		1.824	
Di Gliulio, P et al	Expanding the role of the nurse in clinical trials: the nursing summaries.	Cancer Nursing, 1996, Vol 19, no 5, pg 343 – 347.	Anecdotal	Implementation of nursing summaries to support safe implementation of research protocol.	No	No	1.824	Identified 4 distinct duties and roles that seemed to be common to all CRN posts.

Author	Paper Title	Journal, Year, volume, issue and page	Empirical research or anecdotal?	Focus of paper? - CRN experience - Workforce structure - Role responsibilities - Patient care - Other	How does the paper answer the research question?		Impact factor	Additional comments
					Does it explore the experience of CRNs within their role?	Does it explore the experience of other research staff concerning the CRN workforce?		
Houston, C	The role of the research nurse in translating evidence into practice.	Nursing Management,2012, Vol 19, no 1, pg 25 – 27.	Anecdotal	Article explores the role of the research nurse in supporting changes in practice and discusses how clinical teams benefit from participating in research.	No		Nil	
Walsh, C	A practice research nurse.	Practice Nursing, 2010, Vol 21, no 2, pg 102.	Anecdotal	Personal account of CRN role.	No		Nil	Discusses role responsibilities.
Chester, P et al	Clinical research networks in diabetes: the evolving role of the research nurse.	European Diabetes Nursing, 2007, Vol 4, no 1, pg 10 – 13.	Anecdotal	Overview of research nurse role and set up of research networks.	No		0.43	
Legge, S	The research nurse in orthopaedics.	Journal of Orthopaedic Nursing, 2004, Vol 8, pg 20 – 24.	Anecdotal	Personal account of being a research nurse.	Yes		0.561	Very descriptive account. Does not discuss challenges.
Hardicre, J	An exploration of the role of the research nurse and its impact.	British Journal of Nursing, 2013, Vol 22, no 3.	Anecdotal.	Exploration of the role of the research nurse.	No		0.53	Personal account of working as a research nurse.
Oyebode, C	A day in the life of	European Journal of Palliative Care, 2012, Vol 19, no 2, pg 91 – 92.	Anecdotal	Personal account of CRN role.	Yes		0.34	Gives an account of a typical day as a research nurse.
Johnson, S & Stevenson, K.	Nursing research or research nursing? Two separate terms, two separate careers.	Nurse Researcher, Vol 17, no 3, pg 32 – 40.	Anecdotal	Considers skills required in research nursing and highlights importance of the role.	No		1.356	
Beane, C & Auld, L	Paediatric oncology research nursing: improving the service	British Journal of Nursing, 2002, Vol 11, no 9, pg 626 - 633	Anecdotal	Covers the setting of core standards for running of research studies.	No	No	0.53	
Sewell, J	HIV Research Nurse and PhD student	Gastrointestinal Nursing, 2015, Vol 13, no 3,pg 50	Anecdotal	Reflections of working as a research nurse whilst doing a PhD.	No	No	0.13	
Mais, K	The role of the research nurse in hospital based oncology clinical trials	Nursing Journal, 2006, Vol 1, no 3, pg 22 - 23	Anecdotal	Over view of the responsibilities of the research nurse in Oncology.	No	No		

Author	Paper Title	Journal, Year, volume, issue and page	Empirical research or anecdotal?	Focus of paper? - CRN experience - Workforce structure - Role responsibilities - Patient care - Other	How does the paper answer the research question?		Impact factor	Additional comments
					Does it explore the experience of CRNs within their role?	Does it explore the experience of other research staff concerning the CRN workforce?		
Stephens-Lloyd, A	The extended role of the clinical research nurse: Building an evidence base for practice.	Nursing Times Research, 2004, Vol 9, no 4, pg 18 – 27.	Anecdotal	Illustrates the extended responsibilities of the CRN.	No	No	0.12	
Kenkre,J & Foxcroft, D.R	Career pathways in research: clinical research	Nursing Standard, 2001, Vol 16, no 5, pg 41 – 43.	Anecdotal	Overview of requirements for role as a research nurse and career structure	No	No	0.08	
Kenkre, J & Chatfield, D	Study Site Co-ordinator/ Clinical Research Nurse	Clinical Research Focus, Vol 15, No 5, pg 5 – 9.	Anecdotal	Overview of research nurse role and skills required.	No	No	1.85	
Watmough, S, Flynn, M & Wright, A	Research nurse or nurse researcher?	British Journal of Cardiac Nursing, 2010, Vol 5, no 8, pg 396 – 399.	Anecdotal	Discusses differences in the role of research nurse and nurse researcher.	No	No		
Deave, T	Research nurse or nurse researcher: How much value is placed on research undertaken by nurses?	Journal of Research in Nursing, 2005, Vol 10, no 6, pg 649 – 657.	Anecdotal	Highlights the distinction between the research nurse and nurse researcher.	No	No		
Reay, H and Sears, J	A collaborative model for training clinical research staff.	Nursing Management, 2013, Vol 20, no 3, pg 22 – 27.	Anecdotal	Discusses the set up of a collaborative training model for research staff.	No	No		
Jones, H, Croudass, A & Lewis, S	Facilitating the link between research and clinical practice	Cancer Nursing Practice, 2010, Vol 9, no 10, pg 23 - 26	Anecdotal	Overview of research nurse role supported by a cancer charity.	No	No		
Gordon, C	Exploring the new speciality of clinical research nursing	Nursing Times.net, 2008	Anecdotal	Overview of developments within the research and the CRN role.	No	No	0.12	
Sandhu, K	From expert to novice: Role transition from nurse to clinical research nurse	The Journal of Clinical Research & GCP. 2014, June 18	Empirical research	Online survey to explore and describes CRN perceptions of role transition.	Yes	No		Used a general inductive mixed methods approach based on grounded theory. 309 responses.

Author	Paper Title	Journal, Year, volume, issue and page	Empirical research or anecdotal?	Focus of paper? - CRN experience - Workforce structure - Role responsibilities - Patient care - Other	How does the paper answer the research question?		Impact factor	Additional comments
					Does it explore the experience of CRNs within their role?	Does it explore the experience of other research staff concerning the CRN workforce?		
Gregory, S, Oettle, R & Hayes, G	A model for research nurses managing risk and study delivery strategies	Clinical Research and GCP, 2015, October 12	Anecdotal	Overview of training session to examine the components of the research nurse role.	No	No		
Bird, J and Kirshbaum, M	Towards a frame work of advanced nursing practice for the CRN in cancer care.	Clinical Effectiveness in Nursing, 2006, Vol 9, no 3-4, pg 161 – 171.	Literature review	To explore the role of the CRN in cancer care and consider whether it can be viewed as an Advanced Nurse Practitioner.	No	No		Reviewed literature of CRN role in cancer care between 2000 and 2005.
James, N & Armitage, F	The importance of clinical trials in cancer care.	Cancer Nursing Practice, Vol 1, no 9, pg 24 – 29.	Anecdotal	Overview of clinical trials in cancer and responsibilities of the CRN.	No	No		
Willems, Y & Gumbrell, L	Cancer Care and the research nurse	Nursing Standard, 1990, Vol 5, No 6, pg 30 -32	Anecdotal	Overview of research nurse role	No	No		
Jones ,H	Clinical Research Nurse or Nurse Researcher.	Nursing Times, 2015,	Anecdotal	Overview of differences between Nurse Researcher role and Research Nurse role.	No	No		36
Bishop, V	Colleague, Collaborator or handmaiden? ... the role of the CRN	Nursing Times, 1983 , 156 (25) pg 31 – 33.	Anecdotal	Overview of research nurse role	No	No		

Appendix 8. Study timeline



Appendix 9. Expert Review Panel members

Reviewer	Current role	Years working in clinical research	Range of experience	Number of research roles held
Reviewer 1 Research publications and reports = 11	Head of Organisational and Workforce Development – National Research Organisation	20 years	Worked as nurse researcher for 10 years. Looked at nurse practice development. Current role has responsibility for research delivery workforce who have responsibility for nationally funded research programmes. Includes leadership for GCP training programme.	Led 4 national research projects and now current role.
Reviewer 2 Research Publications = 7	Research Network Director – National network	16 years	Initially held research nurse posts. Developed research nurse workforce. Advised on workforce requirements for successful national bids for funding streams. Local, regional and national organisational reviews of research infrastructure. Member of National research committees. Involved in CRN Competency framework.	4 different roles but current post comprises 2 components.
Reviewer 3 Research Publications : - 30 Papers - 10 book chapters	Professor of Nursing	26 years	Lecturer in Research Methodology Academic Supervisor Global knowledge of CRN role Experienced researcher and Supervisor Involved in national work streams which support development of the CRN role. On board of RCN Research Society On Editorial board of two peer review journals.	No research nurse roles
Reviewer 4 No publications	Clinical Research Facility (CRF) Manager	15 years	Has worked as a CRN for most of nursing career mainly specialising in Oncology before current role. Now manages a CRF with 4 dedicated staff and overseeing other research teams when using the facility.	4 roles
Reviewer 5 Publications about CRN role and education.	Cancer Network Manager	20 years	Manager of topic specific network. Manages large team of research nurses, Data Managers and Trial co-ordinators. Involved in education and training of research nurses.	4 roles

Initials	Current role	Years working in clinical research	Range of experience	Number of research roles held
Reviewer 6 No publications	Clinical Research Facility (CRF) Manager	15 years	Has worked as a research nurse for 15 years across 5 different roles. Has also worked oversees. Currently works as a nurse manager of a CRF and oversees a small team of CRNs.	5 roles
Reviewer 7 Research Publications = 4	Associate Director of Academic and Clinical Research Education - University	17 years	Worked as Research Nurse for 3 years alongside Consultant and then moved to a dedicated research unit (now Clinical Research Facility) for 10 years . Has spent the last 6 years developing and delivering Clinical Research courses for people working in Clinical Research both hospital and drug company. Courses run nationally and overseas.	3 roles
Reviewer 8 Research Publications = 3	Senior research nurse working for a charity	15 years	Has worked as an oncology research nurse within various tumour groups. Now works for national charity and oversees a team of CRN based across the UK.	3 roles

Appendix 10. Expert Review panel feedback template

Feedback Sheet

Expert Review panel.

Dear Expert Review panel,

Many thanks for agreeing to help me with this part of my Doctorate Research study. I really am very grateful for your time and support with this. As you are aware I am doing a study to look at the Organisational structure of Research Nurse Teams across University Hospitals. There is currently very little published literature as to how organisations structure their research nurse teams. Sheffield published their structure in 2006 but since the NIHR was established the number of research nurse posts has greatly increased and this has undoubtedly impacted on the set up of research nurse workforce structures across the UK.

This questionnaire has been structured around a framework which identified the six challenges of Quality Improvement within healthcare organisations. It was developed by Bate, Mendel and Robert (2008). These challenges are Structural, Educational, Cultural, Emotional, Political and Technological. The initial section looks at the general demographics of the workforce and there is then a section for each challenge giving a total of 7 sections within the questionnaire. The questionnaire will be sent to the Lead Research Nurse with a trust wide remit at each organisation.

I would appreciate it if you could please take some time to evaluate the questionnaire as follows:

- Please click on the link included in the covering e mail and complete the online questionnaire.
- Please then complete the review template below. Please provide additional comments where possible as this will help to guide me when I review your feedback.
- I have attached a PDF of the questionnaire. Please print and provide further feedback by annotating the questionnaire with your comments. Please return this by post to me or scan and return by e mail.

I would be very grateful if you could return your feedback to me by Friday 11th October so that I can start my analysis.

Once again, many thanks for your assistance with this,
Kind Regards,

Helen

Helen Jones – DHC Student, Kings College London.

References:

Bate, P, Mendel, P and Robert, G (2008) Organising for Quality – the improvement journeys of leading hospitals in Europe and the United States. Radcliffe Publishing, Oxford.

Questionnaire Review

1. How long did it take you to complete the questionnaire (Minutes)	

2. Did you have any difficulties understanding the questions? (Yes/No)	
If Yes, please give details:	

3. Did you have any difficulties completing or scoring the questions? (Yes/No)	
If Yes, please give details:	

4. Did you have any difficulties with the layout of the questions, or appearance of the questionnaire? (For example – with the size of the font, etc) (Yes/No)	
If Yes, please give details:	

5. Did have any other difficulties with the questionnaire? (Yes/No)	
If Yes, please give details:	

6. Where there any questions that you particularly disliked or liked? (Yes/No)	
If Yes, please give details:	

7. How did you feel filling in the questionnaire? Did you experience any specific emotions?

8. Do you think that there is anything else that I should have included in this questionnaire – which I might have missed out? Do you have any suggestions?

9. Please add any further comments or suggestions which you think may be useful.

Appendix 11. Pilot summary for NCRN Newsletter (December 2013)

As part of my Doctorate studies I am carrying out a research project to explore the current organisational structure of the UK Clinical Research Nurse (CRN) workforce. The study aims to examine how research nurse teams are organised within different NHS Hospital Trusts, and how this impacts, for example, on the size of the research portfolio, recruitment data and research nurse workforce management. This is the first ever national study of the UK CRN workforce and will provide important information about the role and the structures within which it is based.

The initial phase is to send a questionnaire survey to Lead Research Nurses with a trust wide remit. I would like to pilot my questionnaire with the NCRN managers. Having worked as a Lead Cancer Research Nurse in my previous role I have experience of the Cancer Research networks. The establishment of the Cancer Research networks marked the beginning of an identifiable structure within which research nurses could be based. The networks provide a well developed structure for CRNs and associated research support roles and afford the opportunity to pilot my questionnaire with a small number of the main study population. Pilot work will also provide important information about the current Cancer Research Nurse workforce prior to the change in the UK network structure. I am aware that the current transition to the new network structure is a time of uncertainty and anxiety. I am, therefore, very grateful for your support with my research study. Please click on the link below to access the questionnaire or paste into your computer.

https://www.surveymonkey.com/s/ukcrnstructuresurvey

Appendix 12. Pilot study report

Pilot Study Report - Cancer Research Network Managers – March 2014

A mixed methods study to examine the organisational structure of research nurse teams within all acute trusts across England.

This was the pilot phase of my Doctoral research project. Cancer Research Network Managers were invited to complete an online questionnaire survey. A brief summary of the study and link to the questionnaire on survey monkey was included in their December newsletter which was sent out from the co-ordinating centre in Leeds. Survey responses were completed throughout December 2013 and early January 2014. The purpose of this report is to provide some initial feedback to the Cancer Research Networks who took part in the survey. The organisation of the research networks across England is currently in transition and will change from April 2014. This will alter the structure and the current 102 topic specific research networks will change to 15 geographical research networks. This will lead to a change in the structure of the current research nurse teams. This report has therefore been written with the specific intention of providing feedback to the networks concerning the results obtained.

The main study population for my Doctoral study will be lead research nurses with a trust-wide remit to their role at all acute trusts across the UK. A large proportion of the Research Nurse workforce across the UK is thought to be wholly or partly structured within the research network system which is funded by the Department of Health via the National Institute of Health Research (NIHR). The Cancer Research Networks were the first topic specific network to be established following the publication of the NHS Cancer Plan in 2000. As each network comprises of a Network Manager who oversees a research nurse workforce they represented the most similar model to the main study population and so were chosen for the pilot phase of my Doctoral research project.

There are currently 32 Cancer Research Network Managers across England. Of these the survey was started by 22 individuals and completed by 14. One survey contained no responses. All remaining 21 surveys contained answers to at least 50% of questions unless they were optional and linked to a previous question. The survey asked for the name of the respondent's organisation but this was an optional question. Fifty per cent of respondents stated their network. This showed good geographical cover of responses with completed surveys received from the south to the north of England. There was however no pattern

evident in those who had not stated their location or responded. The average time in post of the respondents was 5.5 years with the range being from 1 year to 11 years in the post. Of these 47.5% (10/21) were the only person to have held the post and 52.5% were the second or subsequent post holder. The survey was completed by a variety of post holders who self-identified as follows: Research Network Manager (n = 9), Lead Research Nurse (n = 5), Senior Trials Nurse (n = 4), Nurse Consultant (n = 2) and Research Matron (n = 1). The majority of the respondents (81% = 17/21) were on band 8 of the agenda for change scale with 47.5% of these (10/21) on a band 8a. The remaining 19% (4/21) were on a band 7. The study group were working within Cancer Research networks and so - as expected - 75% (15/21) were wholly or partly funded by the NIHR. Other sources which contributed to the funding of the respondents post included Nursing departments (10% = 2/20), Charity grants (15% = 3/20), Academic grants (5% = 1/20) and other undefined sources (10% = 2/20).

The survey was structured around a framework which identifies and examines 6 universal challenges of Quality Improvement within hospitals (Bate, Mendel and Robert, 2008). The challenges are structural, educational, political, cultural, emotional and technological. The authors propose that these challenges are "problems which any organisation will need to find solutions that will work for them in their particular context and if they do not will ultimately lead to disappointment and failure in their quality improvement " (pg 167). In addition the authors add that "different kinds of failure are associated with each of the six challenges" (pg 173). It was chosen as corresponding and relevant to the challenges of implementing and sustaining an organisation-wide approach to research nursing teams. Within the survey, questions were asked which corresponded to all of these challenges although they were not directly identified within these headings. The report will be structured around the following sections which encompass these challenges. These are:

- Research Structure
- Workforce structure
- Organisation and Clinical Environment
- Training
- Information Technology

Research Structure

The majority of respondents (93%, 14/15) confirmed that their research nurse workforce was embedded within a defined research structure. Within this 80% (12/15) said they worked as part of the Comprehensive Clinical Research Network or within a topic specific network. This was as expected considering the target audience but it will be interesting to compare these results with those of the general survey across all acute trusts. Further responses related to the research structure reveal that 26.7% (4/15) also work within an Experimental Cancer Medicine Centre (ECMC), 6.7% (1/15) have been assigned as one of the NIHR Biomedical Research Centres (BRC) and 26.7% (4/15) have one or more Clinical Research Facilities (CRFs).

Looking at the research nurse workload and research portfolio, 62.5% (10/16) said that their nurses were assigned to a mixed portfolio of NIHR and pharmaceutical sponsored studies, 18.8% (3/16) stated they had research nurses who only worked on pharmaceutical sponsored studies and 37.5% (6/16) stated that they had research nurses who only worked on studies that were on the NIHR portfolio. Only 2 respondents (12.5%) said that their research nurses worked within a CRF which is surprising as 26.7% (4/15) had already stated that they had one or more CRFs within their organisation. Regarding the funding of their workforce to support this activity, 94% (15/16) stated that their workforce received NIHR funding, 56.3% (9/16) received pharmaceutical funding, 18.8% (3/16) received funding from a research grant or the nursing directorate, and 37.5% (6/16) received funding from a charity grant. The extent of NIHR funding was as expected but again, it will be interesting to see the comparison with the results of the larger study in due course.

Looking at the management and running of the studies 40% (6/15) agreed or strongly agreed that the Principal Investigators (PIs) were actively involved in all stages and regularly checked on study and patient progress. However, 40% (6/15) were neutral to this statement and 20% (3/15) disagreed with it. Looking into this in more detail 65% (10/15) of respondents felt that the PIs regularly engage with the study progress but leave the research nurses to take overall management of their project and 60% (9/15) agreed that it can be difficult to involve the PIs in the day to day leadership of their projects. Comments include:

"Some PIs are actively involved but some just sign up for the trial and then leave all the responsibilities
with the Research Nurses"

"Some require constant reminders of their PI responsibilities"
"PI engagement is ongoing. We have a good working relationship with our PIs and communicate
regularly, but they leave the overall management to the Research nurses and teams due to their
time and clinic commitments"

Workforce structure

The questionnaire survey examines how the research nurse teams are structured with the following results:

Working within clinical teams with non research colleagues	7.1 % (1/14)
Working directly with Consultants on their research studies	14.3 % (2/14)
Working within a Clinical Research Facility	21.4 % (3/14)
Working in one clinical area in different research teams	35.7 % (5/14)
In a structured research team within one clinical area	64.3 % (9/14)

Table 1 – Team structure that research nurses work within

Therefore, as anticipated for this pilot population most research nurses worked in structured teams within one clinical area. However, it is interesting to note that for some there was more than one working pattern as demonstrated above. In the same way the respondents provided information about the varied funding sources of their research nurse workforce. As expected 94% confirmed funding came from the NIHR. However other funding streams included 56% (9/16) from pharmaceutical companies, 19% (3/16) from research grants, 19% (3/16) from the nursing directorate and 37.5% (6/16) form charity grants.

As the pilot study only looked at teams within one clinical area it will be interesting to see what the main results show as it will indicate the structure across a whole organisation. Looking at the individuals working within these teams the main workforce was as expected with 100% (16/16) respondents having research nurses and 87.5% (14/16) having senior research nurses. However, beyond this there was a range of post holders supporting the research portfolio as shown in table 1.

Post holder	Response percent	Response count (Total = 16)
Clinical Research Nurse	100	16
Senior Clinical Research Nurse	87.5	14
Research Matron	19	3

Clinical Research Facility Manager	12	2
Data Manager	87	14
Clinical Trial Co-ordinator	93	15
Research Assistant	25	4
Research Health Care Assistant	25	4
Research Phlebotomist	6	1
Research Pharmacist	50	8
Quality Assurance Manager	31	5
Laboratory Assistant	37	6

Table 2 – Roles within research teams

Other roles not listed as options but stated by the respondents include Pharmacy Technician, Research Radiographer and Regulatory Officer. Therefore within this there are 15 different roles that could potentially support the delivery of the research portfolio. This aspect will be looked at in the main survey and if appropriate could be examined in more detail within the case studies in order to gain an understanding as to whether this benefits or hampers the research process.

The wider study of acute trusts will identify whether the research nurse workforce has been reviewed and this information will help inform which organisations will be selected as part of the case study phase of the project. Case studies will be decided on size of organisation and time since review and restructure and controls will be decided on size of organisation. Exact indicators will be decided during the analysis of the main study survey but steps will be taken to ensure the cases are representative of the study population and the controls are well matched. Within this pilot group 55% (11/20) stated that their research nurse workforce had been reviewed; based on the results of the review, 31% (5/16) said that the workforce was restructured and a further 31% (5/16) said that changes were made within teams but the whole workforce was not restructured. Based on the comments provided there was a general theme that informal, ongoing review also generally occurred annually. Comments related to this included:

"our workforce is reviewed annually and on staff leaving the post"

" ongoing workforce review to meet demands of a changing research environment"

"informally ongoing review"

The greatest change that appears to have taken place following the workforce review is the introduction of non-nursing research related roles. From the comments received there was a general theme that Clinical Trial assistants or co-ordinators had been introduced into the team. The survey did not provide the opportunity to allow the respondents to give further information regarding this but where appropriate this issue could be explored further in the main case study phase of the project.

Looking at the appointment of research nurses, 54% (7/13) confirmed this was through the Research and Development department and 61.5% (8/13) confirmed that the nurses were appointed directly by the research teams. Only 23% (3/13) confirmed that the nurses were appointed by the research teams but via Research and Development. This is worth noting as 94% (15/16) respondents had also confirmed that their nurses were funded by the NIHR. As this funding is generally managed by R and D it is interesting to note that they are not directly involved with the appointment of nurses. This point will be explored further in the main study when carrying out the more in depth case studies. Other methods of appointing the research nurses were 15% directly by clinical teams (2/13), 15% directly by Consultants (2/13) , 23% (3/13) via their partner university and 15% (2/13) through the hospital nursing bank. This demonstrates that the recruitment processes across the organisation are not consistent. This may therefore impact on whether it is possible to use a common system to appoint the research nurse workforce. For example the survey highlighted a lack of a consistent process for the management of job descriptions (JD). Results show that 31% (5/16) of respondents employed their nurses on a generic JD for each banding level, 37.5% (6/16) had JDs written for each research nurse role by the individual department and 44% (7/16) used a generic JD which was then adapted to suit the needs of the post. This point is highlighted as organisations that are known to have restructured their research nurse workforce have introduced a system of consistent JDs.,

The Organisation and the Clinical Environment

The awareness of research within the organisation and experience of research nurses in the clinical environment was also examined. Eighty-five % of respondents (17/20) agreed or

strongly agreed that research was considered important and relevant within their organisation, and 70% (14/20) said that staff recognised the importance of research and were keen to support its success. However, only 55% (11/20) agreed or strongly agreed that senior nursing staff across the organisation considered that research was important, Looking at the awareness of staff within the organisation of the importance of research to the national NHS research agenda, 80% said they were very aware or somewhat aware. To support this 60% disagreed or strongly disagreed that research was generally misunderstood and there was little support for its success. When asked whether research was low on people's agenda due to the importance and workload implications of government targets, initiatives and reports, 35 % (7/20) either agreed or strongly agreed; 35% (7/20) said they disagreed or strongly disagreed. This seems to show that the reality of the day-to-day importance of research related to other clinical priorities differed to the perception and opinion of its importance.

Looking at the Cancer research nurse workforce within the organisation 95% (19/20) said that clinical staff were aware or very aware of them. However, only 37% (7/19) felt that nursing colleagues understood the research nurse role. Comments related to this included

" I think this is getting better but I think in the main it is still seen as data management"

"The clinical research nurse role seems to be misunderstood by many nursing colleagues including some of the PIs we work alongside"

" there has been a view that the role is all about data collection and filling out forms"

" variable. Some do some don't. They often don't see the complexity of the role".

Looking at support given to research by those in a clinical role, 80% (16/20) said that non-research colleagues would help to facilitate research and 82.5% (14/17) said that staff would inform research nurses about patients who may be suitable for studies. This is confirmed by the amount of direct support received: 82.5% (16/19) said that staff were willing to collect a small amount of research data if seeing patients as part of a clinical appointment. However, the direct comments received regarding this were varied and include:

"some are happy to flag up potential trial patients to the research teams but do not have the time

to focus on understanding portfolio of studies due to their own heavy workloads"

"its hard to generalise. Some staff are very research savvy. Others so very busy within their role

they are not engaged"

"some staff are not very willing as this is considered to be additional work which they could

well do without"

Due to the limited amount of comments it is difficult to identify distinct themes. However, the impression gained is that although non-research staff are willing to support the research nurses, the reality of the busy clinical environment prevents this from effectively taking place.

Looking at the clinical staff attitude to the individual studies the results were positive. 72% (13/18) said that staff were interested in the studies and willing to remain updated regarding new protocols, 50% (10/20) agreed or strongly agreed that clinical staff were keen to learn about new studies and receive regular formal or informal updates and 80% (16/20) said that staff were very aware or somewhat aware of the volume of studies running within the organisation. This demonstrates that overall respondents felt there was a good awareness and positive response to the studies being run.

Looking at support in the clinical environment, 60% (12/20) said their nurses felt welcome and were allocated dedicated space to see their research patients and 71.5% (10/14) said that their research nurses felt accepted within the clinical environment by their nursing colleagues and efforts were made to accommodate their requirements. However, 65% (13/20) agreed or strongly agreed that the research nurses frequently commented on the difficulty of seeing patients in the clinical environment and being unable to spend the required amount of time with the patient. When these 2 questions were analysed together 35% (7/20) had agreed that their nurses felt welcome in the clinical environment but commented on the difficulty of seeing patients there. Although 80% (16/20) felt that clinical staff would willingly notify the research nurses when their patients arrived in the department

or had completed their clinical appointment, 50% (10/20) agreed that research nurses reported that patients were still sometimes missed in the clinical environment. When asked whether nurses found the clinical environment a difficult working environment 46 % (6/13) either disagreed or strongly disagreed with this, compared to 31% (4/13) who agreed and 23% (3/14) who felt neutral to this statement. Comments related to this included:

"The early phase team have their own dedicated space. Late phase staff have more difficulty and

depending on tumour site have very different experiences. Some clinics have no space for

research staff or seeing research patients".

"often lack of space to talk to patients in clinic environment"

"The problem is clinic space. The clinical staff in OPA departments are very helpful and interested and will

Work with the RNs and accommodate as much as they can, but this is hindered by the lack of

Clinic space and clinic time slots".

"space to see patients in outpatient clinics is very limited"

"I manage a team on a dedicated research facility so we rarely have to see patients in clinical environments. When we do it can be challenging as space is at a premium".

From these answers it seems that in general the clinical nurses are supportive of research and make efforts to accommodate the research nurses requirements. However, it is factors outside their control such as space to see patients within the clinic that appears to affect the experience the research nurse has of seeing patients within the clinical environment. Those research units that have their own dedicated space did not state this as an issue. .

Training

The framework which the survey was structured around identifies learning as one of the challenges an organisation must address "to begin to accumulate and pass on the

knowledge and lessons“ (Bate, Mendel and Robert, 2008: 172). Included within this is the provision of training opportunities and support for staff for further academic study. Within this survey 84% of respondents (16/19) felt that their organisation supported the further professional development of nurses. The remaining 16% (3/19) were not sure regarding this question. Looking further into the training provided for newly appointed research nurses, 93% (14/15) stated that they attended a Corporate trust induction programme, 89% (8/9) stated that they attended a trust nursing induction programme and 100% stated that they attended a local and research induction programme. There are numerous components within a research nurse role that require attendance at a formal training programme. The survey sought information on which of these training programmes were provided. Individual questions were directed to generic and research related training programmes. The results showed there were differences in the responsibilities of the research nurses across organisations. This included more specialist skills including physical examination skills, ECG interpretation and chemotherapy administration. The 2 charts (figure 1 and figure 2) which follow show the range of responses.

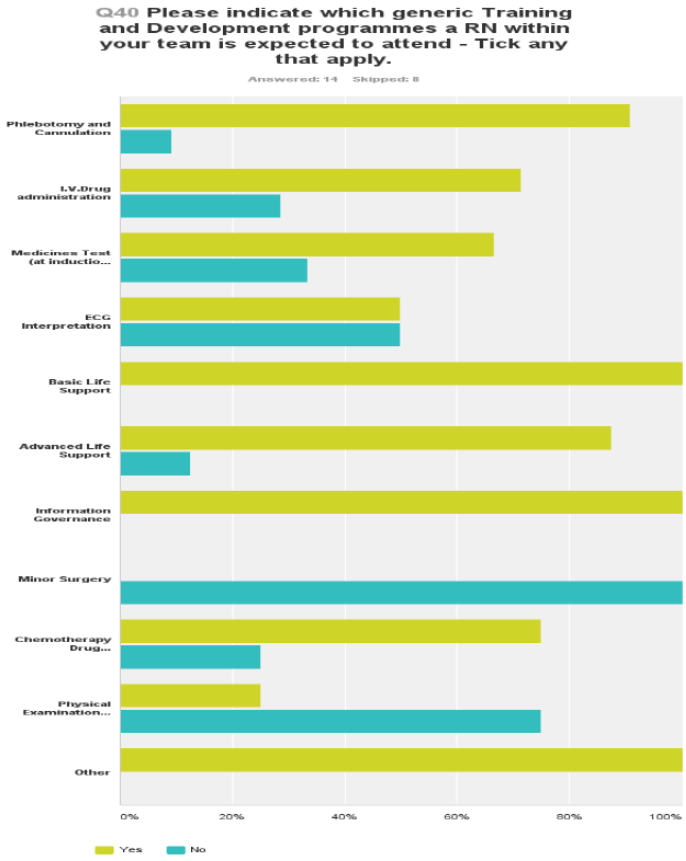


Figure 1 – Generic Training and Development programmes attended by research nurses

Looking at these generic components within the role it is interesting to note the differences across the different organisations. 100% of respondents reported that their nurses were expected to attend training in Basic Life support and Information governance which is relevant to all health professionals in a patient centred role. However, there was not this consistency related to other role related training programmes such as phlebotomy and cannulation, ECG interpretation and chemotherapy drug administration. Considering the requirements of the research nurse role especially related to oncology studies it would be interesting to explore this further to gain a deeper understanding for these differences. However, the response numbers are small and are not consistent across all the answers.

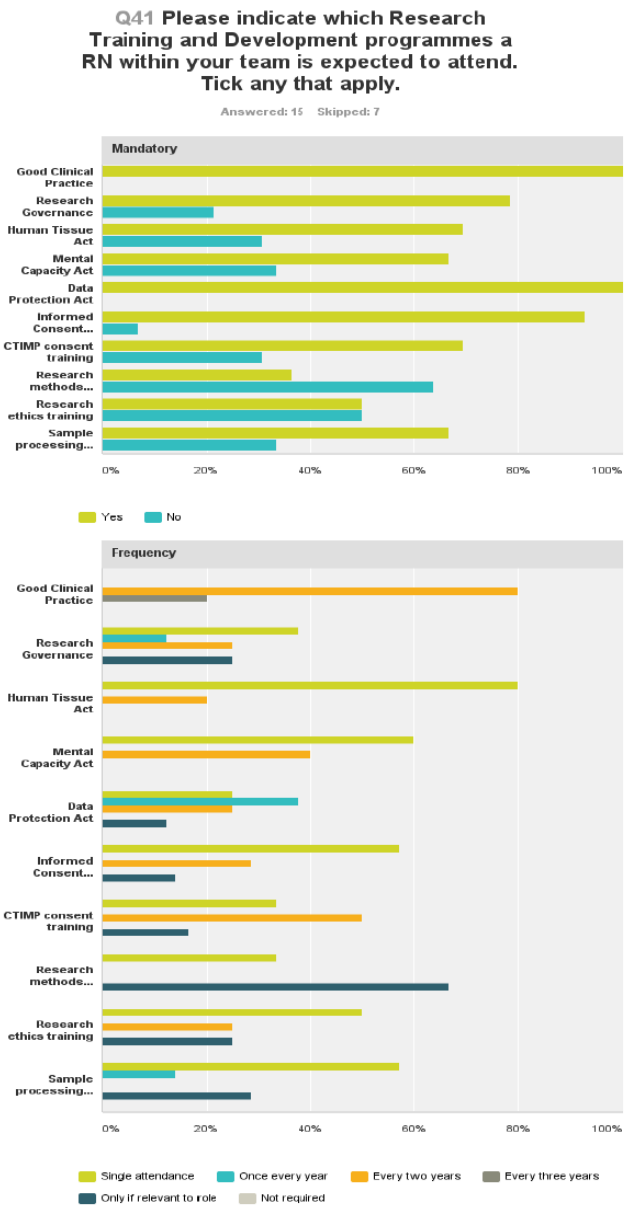


Figure 2 – Research Training and Development programmes attended by research nurses

Research related training covers specific training programmes which are relevant to the research nurse role. GCP is mandatory for research and so as expected 100% (15/15) respondents said their research nurses were required to attend it. However, other research related training which covered knowledge that is required for the role had a mixture of responses as to whether the research nurses were expected to attend them. For example, 78% (11/14) were expected to attend training on Research Governance, 69% (9/13) were expected to attend training on the Human Tissue Act, 50% (5/10) were expected to attend training on Research ethics and 67% (8/12) were expected to attend training on sample processing skills. A reason for this range of responses is provided by one of the respondents who added:

"these aren't necessarily training programmes but skills to be required by on the job learning"

It will be interesting to investigate this issue further within the main study survey and individual case studies.

Related to ongoing training, 53% (8/15) said they provided a regular structured training programme for their research nurses. Seven of these eight respondents (87.5%) provided further information on the frequency of these sessions which varied from annual updates, three or four times a year and 5 or 10 days depending on the programme; there was no consistency in what was considered to be required. Regarding the content of these sessions only 6 responses were received; 3 responses reported that the content was variable and 3 stated that the content was related to research. Whilst the numbers were small - and it is hoped that a greater degree of information regarding this will be gained from the main study survey - this does give a useful overview and demonstrates that some organisations do run their own research specific training programmes.

Related to opportunities for personal study towards academic qualifications 13 responses were received as to whether research nurses could access funding for academic courses. Of these 61.5% (8/13) said their nurses could access internal funding related to their own department, 33% (4/12) said that research nurses could access the same internal funding

that was available for any nurse across the organisation to support academic courses, 42% (5/12) said external funding from the NIHR was available and 27% (3/11) confirmed that external funding from grant award bodies was available. Therefore for most of these funding sources it seems that the research nurses are disadvantaged. However, the survey did not explore whether these funding sources were available to clinical nurses.

The array of academic programmes which the research nurses could access funding for showed inconsistent opportunities as illustrated in the table below.

	Always	Occasionally	Never	Not required
Diploma	18.2% (2/11)	63.6% (7/11)	9.1% (1/11)	9.1% (1/11)
BSc	31% (4/13)	69% (9/13)	0 %	0 %
MSc	8.3% (1/12)	91.7% (11/12)	0 %	0 %
Doctorate programmes	0%	40% (4/10)	30% (3/10)	30% (3/10)
PhD programmes	0%	54.5% (6/11)	18.2% (2/11)	27.3% (3/11)
Individual academic modules related to role.	58.3% (7/12)	41.7% (5/12)	0%	0%

Table 1 – Academic training programmes to which research nurses can access funding for.

From this table above it seems that the majority of research nurses are able to access academic courses up to the level of an MSc qualification. However, it seems that they have less or no access to higher academic qualifications such as a Doctorate or PhD. All respondents said that their research nurses could access individual academic modules related to their role. These questions were asked as the publication of the Finch Report (Developing the Best Research Professionals) in 2007 highlighted the lack of a framework for clinical nurses who wished to progress academically. It recommended that a clinical academic career pathway be funded in order to support the development of nursing clinical

academics. Since that time funding has become available to nurses via the NIHR which they can access in order to gain fellowships to support them studying towards Masters degrees, PhDs and post doctoral research projects. These figures demonstrate that some nurses are currently able to access funding towards these higher degrees which is an improvement compared to a few years ago (find reference showing nurses with PhD before 2007).

Information Technology

The original framework that the survey is based around includes the importance of the technology infrastructure as being involved in an organisation's Quality Improvement. Due to the current Information technology (IT) changes within the healthcare environment affecting patient care it was important to include questions relating to this within the survey. Looking at new IT developments 70 % (14/20) confirmed that they had been introduced within the previous 2 years. All respondents then provided further information on this and 64% (9/14) confirmed that the computer system EDGE had been introduced. EDGE is a computer software system which is used to track patients recruited into clinical trials within the hospital as the internal patient records system is not able to do this. It aims to provide an accurate view of the number of patients involved in clinical trials and demonstrate research activity. It is also used to provide research activity reports to the research networks and the Medicines Healthcare Regulatory Agency (MHRA). Only 20% (3/15) respondents mentioned trust wide changes concerning Electronic Patient Records (EPR). This was surprising as in 2012 the Department of Health (DOH) published its information and technology strategy entitled "The Power of Information. Putting all of us in control of the health and care information we need". The strategy suggested a number of actions that healthcare organisations could take in order to transform information for health and care. These included that "electronic care records progressively become the source for core information used to improve our care, improve services and to inform research" (pg 5) and "the widespread use of modern technology" (pg 6) (DOH 2012). However, only one respondent confirmed that "e hospital implementation is underway" and that it was "unclear how it will work" and another respondent confirmed that "the organisation is moving to Electronic Patient Records (EPR) and research representatives are on the panel". The researcher knows from their own organisation that over the last 12 to 18 months there has been an ongoing project across the trust to implement a trust wide system of electronic patient notes and electronic prescribing, both of which will impact on the running of research studies. Therefore there had been an expectation that more organisations would include information in their responses concerning organisation wide IT changes that had impacted on the collection of data for research studies. This may have been due to the individual interpretation of the question Therefore it may be useful to re phrase this question for the main survey in order to be more specific as to what is required.

Looking at future planned IT developments that may impact on the running of clinical trials and research studies, 65% (11/17) confirmed that they were planned, 6% (1/17) said there

were none planned and 29% (5/17) were unsure. Of those that said they were planned only 36% (4/11) gave further details on trust wide changes such as moving to a paperless system or EPR. As stated 29% were unsure as to the future IT plans for the organisation and so the reality of the impact on research studies of IT changes involving patient records within the NHS may be very different. The main survey population and case studies will be able to provide further details regarding this.

Conclusion:

This pilot study has enabled the survey tool to be piloted and identifies twelve implications for the main study. These are as follows:

1) It identified that 80% of respondents worked within an NIHR structure. It will be interesting to compare these results with those of the general survey as respondents will be across an entire acute trust.

2) It identified that for 94% of respondents, the workforce received NIHR funding . This was as expected due to the nature of the group but it will be interesting to compare this with the results of the main study.

3) The pilot population was based within one clinical area. However, the main survey will be across organisations and so will illustrate the range of clinical areas which research nurses currently work across.

4) This survey highlighted 15 different roles that could potentially support the delivery of the research portfolio. This aspect will be looked at in the main survey and if appropriate could be examined in more detail and within the case studies in order to gain an understanding as to whether this benefits or hampers the research process.

5) The survey asked questions concerning whether the Research Nurse workforce had been reviewed and what actions, if any, were taken on the results of the review. The greatest change appears to have been the introduction of non-nursing research related roles. From the comments received there was a general theme that Clinical Trial assistants or co-ordinators had been introduced into the team. The survey did not provide the opportunity to allow the respondents to give further information regarding this but where appropriate this issue could be explored further in the main case study phase of the project.

6) The survey examined how research nurses are appointed into the organisation and who takes responsibility for this. It identified a mix between R and D and research teams. 94%

(15/16) of respondents had confirmed that their nurses were funded by the NIHR. As this funding may sometimes be managed by R and D it is interesting to note that they are not directly involved with the appointment of all research nurses. This point will be explored further in the main study when carrying out the more in depth case studies.

7) The survey sought information on which training programmes were provided for research nurses. Individual questions were directed to generic and research related training programmes. The results showed there were differences in the responsibilities and training requirements of the research nurses across organisations. It will therefore be interesting to explore this further to gain a deeper understanding for these differences.

8) Research related training covers specific training programmes which are relevant to the research nurse role. GCP is mandatory for research and so as expected 100% (15/15) respondents said their research nurses were required to attend it. However, other research related training which covered knowledge that is required for the role had a mixture of responses as to whether the research nurses were expected to attend training programmes for them. One comment related to this stated that some skills were not necessarily covered by training "but skills to be required by on the job training". It will be interesting to investigate this further within the main study survey and individual case studies.

9) The survey included a section on the changes related to information technology (IT). However, responses were mainly related to research based IT changes, such as the implementation of EDGE, and not those related to trust wide organisation IT changes. Therefore it may be useful to re phrase this question for the main survey in order to be more specific as to what is required.

10) Looking at future planned IT developments that may impact on the running of clinical trials and research studies, 65% (11/17) confirmed that they were planned, 6% (1/17) said there were none planned and 29% (5/17) were unsure. Of those that said they were planned only 36% (4/11) gave further details on trust wide changes such as moving to a paperless system or EPR. As stated 29% were unsure as to the future IT plans for the organisation and so the reality of the impact on research studies of IT changes involving patient records within the NHS may be very different. The main survey population and case studies will be able to provide further details regarding this.

11) Anecdotal data related to the research nurse role has previously suggested that the research nurse role is misunderstood by other nursing colleagues (REF ??). Within this survey only 37% (7/19) felt that their nursing colleagues understood the research nurse role.

Comments from those that didn't included "I think it is getting better but I think in the main it is till seen as data management" and "there has been a view that it is all about data collection and filling out forms". It will therefore be interesting to gain the views of a larger numbers of research nurses within the main survey in order to gain some empirical data on this.

12) The survey provided information on the experience of research nurses within the clinical environment. 80% (16/20) agreed that non research colleagues would help to facilitate research and 71.5% (10/14) said that their research nurses felt accepted within the clinical environment. However, 65% (13/20) indicated that their research nurses frequently commented on the difficulty of seeing patients within the clinical environment. Overall the results suggested that although non research staffs are willing to support the research nurses, the reality of the busy clinical environment prevents this from effectively taking place and some of this may be due to available space. It will therefore be interesting to compare this to the main larger survey and explore this further within the case study phase of the study.

Conclusion.

Although this pilot survey involved small numbers, some important themes have emerged that can be examined further within the main study which will include many more organisations. Therefore overall this pilot survey has been very helpful in allowing the researcher to pilot the tool and also help to identify certain issues that may need further exploration within the main research project.

References

Bate, P, Mendel, P and Robert, G (2008) Organising for Quality. The improvement journeys of leading hospitals in Europe and the United States. Radcliffe Publishing Ltd.

DOH (2012) The Power of Information. Putting all of us in control of the health and care information we need.

Finch, ? (2007) Developing the best research professionals.

Appendix 13. Survey questionnaire

Research Nurse Survey

I would like to invite you to participate in my doctoral project. This survey is being carried out as part of my Doctorate in Healthcare at King's College, London and has been funded by the Biomedical Research Centre at Guys and St Thomas's NHS Foundation Trust. It has received ethical approval from the Kings College London (KCL) College Research Ethics Committee (Psychiatry, Nursing and Midwifery Subcommittee). It comes under the definition of Service Evaluation.

The aim of my survey is to understand how research nurse teams are organised within different NHS Hospital Trusts, and how this impacts on size of the research portfolio, recruitment data and research nurse workforce arrangements. From this it may be possible to identify the most effective organisational structure for Clinical Research Nurses within Hospital Trusts.

You have been identified as the Lead Research Nurse / Research Manager within your organisation. In order to examine the current structure of the research nurse workforce at each of the organisations I would like to invite you to participate in this project by completing this online questionnaire survey which will ask for details concerning your current structure. Survey results will then be evaluated and from this four organisations will be selected to form the case study phase of the project. These organisations will then be examined in further detail.

The research tool "Survey Monkey" has been used as the online questionnaire for this survey. Submission of a partially completed questionnaire (by pressing the "store", "next" or "continue" buttons) implies consent to participate, and for data entered up to this point to be included in the project. Submission of a completed questionnaire (by pressing the "submit" or "finish" buttons) implies consent to participate, and for all data collected to be used. The research tool Survey Monkey has the facility to retain partially completed information. If there is anything that is not clear or you would like more information please contact me using the details below.

You can leave the survey if you wish to return to it at a later date. You will be able to re start where you left it as long as you log on with the same computer.

The survey may take up to 30 minutes to complete.

With many thanks,

Helen Jones
DHC Student - Kings College London
Matron for Research - GSTFT

E mail – Helen.h.jones@kcl.ac.uk

General demographics of your Research Nurse (RN) workforce.

1. Please state the name of your organisation

2. Please state:

The title of your current post

The length of time you have held it

The band of your current post

3. How long has your current role been established?

4. Are you the first person in your current role?

- ◯ Yes
- ◯ No
- ◯ Unsure

5. Please indicate how your current role is funded?

- ☐ NIHR funded
- ☐ Pharmaceutical Company
- ☐ Research Grant - e.g MRC
- ☐ Nursing Directorate
- ☐ Charity grant - e.g CRUK
- ☐ Academic grant via the university
- ☐ Unknown
- ☐ Other - please state

Other (please specify)

6. Has your Research Nurse workforce ever been reviewed?

- ◯ Yes
- ◯ No
- ◯ Not sure

If reviewed state year of review

7. If your RN workforce was reviewed did any action take place based on the results of the review? (Please tick).

- ◯ No
- ◯ CRN workforce was re structured
- ◯ Changes were made within teams but whole workforce was not re structured
- ◯ Other - please specify

Please give further details concerning the review.

8. If Yes to question 6 - Is a report available which outlines the details of the review?

	Yes	No
a) Is a report available which outlines the details of the review?	☐	☐
b) Has the RN workforce been reviewed more than once?	☐	☐
c) Can you provide a copy of this review document for evaluation within this study?	☐	☐

If yes to 8c please forward a copy of the report to helen.h.jones@kcl.ac.uk

Research awareness of the general workforce across your organisation.

9. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
Research is considered important and relevant within your Organisation	◯	◯	◯	◯	◯
Research is considered important by all staff within the Clinical areas	◯	◯	◯	◯	◯
Research is considered important by senior nursing staff across the organisation (band 8 and above)	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

10. Do non research colleagues help to facilitate research?

◯ Yes

◯ No

◯ Unsure

11. If yes to question 10 which of the following statements is true - tick any that apply.

	Yes	No
Staff will inform RNs about patients who may be suitable for the studies	◯	◯
Staff are interested in our studies and willing to remain updated regarding new protocols	◯	◯
Staff are willing to collect a small amount of research data if seeing the patient as part of a clinical appointment	◯	◯

Please provide any further comments below relating to your responses.

12. If no to question 10 please expand your answer

13. Do your nursing colleagues understand the research nurse role?

- ◯ Yes
- ◯ No
- ◯ Not sure

Please explain your answer

14. Does your organisation support the further professional development of nurses ?

- ◯ Yes
- ◯ No
- ◯ Not sure

Please explain your answer

Aspects within the research process that RNs may find challenging.

15. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree
The RNs report that adherence to all research governance requirements is high	◯	◯	◯	◯	◯
The RNs report that attendance to research governance training sessions is high and team members attend updates as required.	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

16. Please rate on the scale the awareness of the staff within your organisation concerning the following:

	Very aware	Somewhat aware	Neutral	Not very aware	Unsure
The presence of a dedicated nurse workforce related to research	◯	◯	◯	◯	◯
The importance of research to the national NHS agenda	◯	◯	◯	◯	◯
The current structure of research within your organisation and the way to access resources to support research studies they may wish to run	◯	◯	◯	◯	◯
The volume of studies currently running within your organisation	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

17. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure
The RNs feel welcome within the clinical environment and are allocated dedicated space to see research patients.	◯	◯	◯	◯	◯	◯
The Clinical staff willingly notify the RNs when research patients arrive in the department or have finished their appointment with the clinical staff.	◯	◯	◯	◯	◯	◯
The RNs frequently comment on the difficulty of seeing patients in the clinical environment and being able to spend the required amount of time with the patient.	◯	◯	◯	◯	◯	◯
The RNs report that patients are sometimes missed as they were not informed about them.	◯	◯	◯	◯	◯	◯
The clinical staff are keen to learn about new studies and receive regular formal or informal updates from the RNs concerning the current research portfolio.	◯	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

18. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure
Staff recognise the importance of research and are keen to support its success	◯	◯	◯	◯	◯	◯
Research is generally misunderstood and so there is little general support for its success	◯	◯	◯	◯	◯	◯
Research is generally low on peoples agenda due to the importance given to, and workload implications, from government targets, initiatives and reports.	◯	◯	◯	◯	◯	◯

Please provide any further comments below relating your responses.

How developments within technology have been incorporated into the research...

19. Has there been any organisation wide IT developments that have been introduced over the last two years? (for example electronic notes)

- ◯ Yes
- ◯ No
- ◯ Not sure

20. If yes to question 19 please give details to illustrate your answer.

21. Have you implemented any research based IT changes over the last two years?

- ◯ Yes
- ◯ No
- ◯ Not sure

22. If yes to question 21 please give details to illustrate your answer.

23. Have new IT developments across your organisation impacted on the data collection within clinical trials?

- ◯ Yes
- ◯ No
- ◯ Not sure
- ◯ Not applicable as no recent IT developments.

If yes please give details to illustrate your answer.

24. Are current IT developments within your organisation used uniformly across your RN teams?

- ◯ Yes
- ◯ No
- ◯ Not sure
- ◯ Not applicable as no recent IT developments.

If yes please give details to illustrate your answer.

25. Are there future planned IT developments that may impact on the running of clinical trials and research studies within your organisation?

- ◯ Yes
- ◯ No
- ◯ Not sure

If yes please give details.

26. Do any of your RNs work across more than one organisation?

- ◯ Yes
- ◯ No
- ◯ Unsure

27. If yes to question 26 , how easy is it to organise the governance requirements for this? - e.g. - Honorary passports / Research passports.

Please indicate with a tick which of the following apply

Very easy - the process is quite smooth	◯
Not so easy - it seems to take longer than necessary	◯
Very difficult - the process is slow and leads to delays in the study.	◯

Other (please specify)

The current structure of your Research Nurse (RN) workforce.

28. How many Research Nurses (RNs) do you currently have in your Organisation?

29. Please give numbers of research nurses in each band and state whether actual or approximate amount. If none please state "none".

Band 5	
Band 6	
Band 7	
Band 8a	
Band 8b	
Band 8c	
Band 9	
University grade 5	
University grade 6	
University grade 7	

30. Please state which Clinical areas the RN roles within your Organisation cover (Tick all that apply)

- [ ] Accident and Emergency
- [ ] Oncology
- [ ] Haematology
- [ ] Cardiovascular
- [ ] Rheumatology
- [ ] Dermatology
- [ ] Dental
- [ ] Diabetes
- [ ] HIV
- [ ] Infection Control
- [ ] Midwifery
- [ ] Gynaecology
- [ ] Paediatrics
- [ ] Primary Care
- [ ] Respiratory
- [ ] Genetics
- [ ] Renal
- [ ] Medicine
- [ ] Care of the Elderly
- [ ] Stroke Research
- [ ] Gastroenterology
- [ ] Critical Care
- [ ] Twins Research
- [ ] Assisted Conception
- [ ] Other - please specify

Other (please specify)

31. Is your RN workforce embedded within a defined research structure? (Please tick)

- ◯ Yes
- ◯ No

Other (please specify)

32. Please indicate which of the following apply (Tick any that apply)

- ☐ Organisation has been assigned as one of the NIHR Biomedical Research Centres
- ☐ Organisation has been assigned as one of the NIHR Biomedical Research Units
- ☐ Organisation is part of an Allied Health Sciences Centre
- ☐ Organisation has one or more Clinical Research Facilities
- ☐ Organisation is part of the Network of Experimental Cancer Medicine Centres (ECMC)
- ☐ RN workforce works as part of the Local Research Networks or within one of the divisions.

If none apply please indicate the current structure

33. Please indicate the team structure that your RNs work within? (Tick any that apply).

- ☐ In a structured research team within one clinical area
- ☐ Working in one area in different research teams
- ☐ Working within clinical teams with non research colleagues
- ☐ Working directly with Consultants on their research studies
- ☐ Working independently in one or more clinical teams but not within a research or clinical team
- ☐ Working within a Clinical Research Facility

Other (please specify)

34. Please indicate which of the following research roles are employed within your organisation.

- [ ] Clinical Research Nurse
- [ ] Senior Clinical Research Nurse
- [ ] Research Matron
- [ ] Clinical Research Facility Manager
- [ ] Data Manager
- [ ] Clinical Trial Co-ordinator
- [ ] Research Assistant
- [ ] Research Health Care Assistant
- [ ] Research Phlebotomist
- [ ] Research Pharmacist
- [ ] Quality Assurance Manager
- [ ] Laboratory Assistant

Other (please specify)

35. Please indicate how your RNs are employed - tick any that apply

- [ ] Employed through Research and Development Department
- [ ] Employed by Research Teams (NHS)
- [ ] Employed by Clinical Teams (NHS)
- [ ] Employed directly by Consultants
- [ ] Employed through partner University
- [ ] Employed via nursing bank

Other (please specify)

36. Please indicate how your RN workforce is funded - tick any that apply

- [ ] NIHR funded
- [ ] Pharmaceutical Company
- [ ] Research grant - e.g. - MRC
- [ ] Nursing Directorate
- [ ] Charity grant - e.g. - CRUK

Other (please specify)

37. Structure of research portfolio. How is the RN workload organised?

- [ ] Assigned to studies on research portfolio only - e.g CLRN, NCRN etc
- [ ] Assigned to Pharmaceutical sponsored studies only
- [ ] Assigned to other NIHR funded studies - e.g - BRC
- [ ] Assigned to single research grant studies
- [ ] Assigned to mixed portfolio of NIHR and Pharmaceutical sponsored studies
- [ ] Working within a Clinical Research Facility
- [ ] Working on own nursing research

Other (please specify)

38. Please indicate which of the following in your organisation are responsible for the line management of RNs - tick any that apply

- [ ] Senior Research Nurse / Research Matron
- [ ] Clinical Research Facility Manager
- [ ] Clinical Nurse Specialist
- [ ] Consultant Nurse
- [ ] Clinical Matron
- [ ] Head of Nursing
- [ ] R and D Manager
- [ ] Consultant
- [ ] Research Fellow
- [ ] Manager (non research)
- [ ] Research Manager (non nursing role)

Other (please specify)

39. Please indicate the process for RN job descriptions (JDs) within your organisation (Tick any that apply).

- [ ] RNs employed on generic research JD per AfC band
- [ ] JDs written for each RN role by individual department
- [ ] Generic JD adapted to suit the needs of the post
- [ ] Unknown

Other (please specify)

Academic profile and training structure of your Research Nurse (RN) workfo...

40. What is the academic profile of your RN workforce? (Please specify numbers in each group if known or state none or unknown)

RGN	
Diploma in Nursing	
BSc	
MSc	
PhD / Professional Doctorate.	

41. Please indicate which of the following induction programmes RNs new into their position are required to attend.

	Yes	No
Corporate Trust Induction	☐	☐
Trust Nursing induction	☐	☐
Local Induction programme	☐	☐
Research Induction programme	☐	☐
Other	☐	☐

Other (please specify)

42. Please indicate which generic Training and Development programmes a RN within your organisation is expected to attend - Tick any that apply.

	Yes	No
Phlebotomy and Cannulation	☐	☐
I.V.Drug administration	☐	☐
Medicines Test (at induction to demonstrate general competence)	☐	☐
ECG Interpretation	☐	☐
Basic Life Support	☐	☐
Advanced Life Support	☐	☐
Information Governance	☐	☐
Minor Surgery	☐	☐
Chemotherapy Drug Administration	☐	☐
Physical Examination skills	☐	☐
Other	☐	☐

Other (please specify)

43. Please indicate which Research Training and Development programmes a RN within your organisation is expected to attend. Tick any that apply.

	Mandatory	Frequency
Good Clinical Practice	☐	☐
Research Governance	☐	☐
Human Tissue Act	☐	☐
Mental Capacity Act	☐	☐
Data Protection Act	☐	☐
Informed Consent training - non CTIMP	☐	☐
CTIMP consent training	☐	☐
Research methods training	☐	☐
Research ethics training	☐	☐
Sample processing skills	☐	☐

Other (please specify)

44. Do you run a regular structured training programme for your research nurse workforce?

- ◯ Yes
- ◯ No

45. If yes to question 44 please supply information on your regular structured training programme for the RNs within your organisation.

Frequency of sessions	
Duration of sessions	
Content of sessions	
Does it include mandatory sessions such as GCP?	
Is it open to those in a non research role?	
Is it open to those working within research in a non nursing role - e.g. Data Managers?	

46. Are RNs within your organisation able to access funding for the following academic training courses?

Diploma	
BSc	
MSc	
Doctorate programmes	
PhD	
Individual academic modules related to role	

47. Please provide further information on the source of funding for academic courses

Internal funding related to own department	
Internal funding available to nurses across the organisation	
External funding from the NIHR	
External funding from grant award bodies	

Other (please specify)

48. Please indicate what study leave arrangements are in place across your organisation that enable the RNs to attend academic courses?

	Yes	No
RNs receive complete study leave allowance regardless of days required.	◯	◯
RNs receive restricted study leave allowance related to organisations study leave policy.	◯	◯
No study leave allowance. Attendance is within individuals own time or annual leave.	◯	◯

Other (please specify)

Approach to research from other colleagues.

49. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure
The PIs are actively involved in all stages of their research projects and regularly check on its overall progress and the progress of the patients involved.	◯	◯	◯	◯	◯	◯
The PIs regularly engage with the progress but leave the RNs to take overall management of their project.	◯	◯	◯	◯	◯	◯
It can be difficult to involve the PIs in the day to day leadership of their projects.	◯	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

50. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure
RNs are made to feel accepted within the clinical environment by their nursing colleagues and efforts are made to accommodate their requirements.	◯	◯	◯	◯	◯	◯
Clinical nurses are happy to help identify suitable patients for studies if asked or collect small amounts of data if requested.	◯	◯	◯	◯	◯	◯
The RNs find the clinical environment a difficult working environment.	◯	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

51. Please rate on the scale your agreement with the following statements

	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Unsure
The RNs within the team are able to express their own ideas and opinions in tem meetings and have an influence on decisions being made.	◯	◯	◯	◯	◯	◯
The research team (PIs and RNs) meet regularly at a dedicated research meeting and individual PIs discuss the studies they would like to set up taking into account the current capacity of the research nurse workload.	◯	◯	◯	◯	◯	◯
My staff turnover is no different compared to the general nurse workforce in my organisation.	◯	◯	◯	◯	◯	◯

Please provide any further comments below relating to your responses.

***52. The next phase of my project involves a case study of 4 organisations which I will visit to carry out the following data collection:**

- Focus group with research nurses

- Interview with Lead Research Nurse (if in post)

- Interview with Principal Investigator

- Interview with R and D Manager

Would you be willing for your organisation to take part in this phase

◯ Yes

◯ No

53. If yes to question 52 please give your name , post title and e mail address

54. Many thanks for completing this questionnaire survey. Please give any further information you would like to add.

55. Would you be willing for me to contact you if required to discuss any of your answers in more detail? If yes please give e mail address. Many Thanks.

56. Many thanks for your time and support in the completion of this survey.

Helen Jones

Appendix 14. Ethics approval

Research Ethics Office

5.11 Franklin Wilkins Building
(Waterloo Bridge Wing)
Stamford Street
London SE1 9NH
Tel 020 7848 4077/4070/3758
Email rec@kcl.ac.uk
www.kcl.ac.uk/research/ethics

KING'S College LONDON

Dr Helen Jones
102 Batchwood Drive
St Albans
Hertfordshire
AL3 5SA

06 August 2013

Dear Dr Jones

PNM/12/13-123 A mixed methods study to determine the impact of different workforce structures within University Hospital Trusts on the Clinical Research Nurse workforce.

Review Outcome: Full Approval

Thank you for sending in the amendments/clarifications requested to the above project. I am pleased to inform you that these meet the requirements of the PNM RESC and therefore that full approval is now granted.

Please ensure that you follow all relevant guidance as laid out in the King's College London Guidelines on Good Practice in Academic Research (http://www.kcl.ac.uk/college/policyzone/index.php?id=247).

For your information ethical approval is granted until **06 August 2015**. If you need approval beyond this point you will need to apply for an extension to approval at least two weeks prior to this explaining why the extension is needed, (please note however that a full re-application will not be necessary unless the protocol has changed). You should also note that if your approval is for one year, you will not be sent a reminder when it is due to lapse.

Ethical approval is required to cover the duration of the research study, up to the conclusion of the research. The conclusion of the research is defined as the final date or event detailed in the study description section of your approved application form (usually the end of data collection when all work with human participants will have been completed), not the completion of data analysis or publication of the results. For projects that only involve the further analysis of pre-existing data, approval must cover any period during which the researcher will be accessing or evaluating individual sensitive and/or un-anonymised records. Note that after the point at which ethical approval for your study is no longer required due to the study being complete (as per the above definitions), you will still need to ensure all research data/records management and storage procedures agreed to as part of your application are adhered to and carried out accordingly.

If you do not start the project within three months of this letter please contact the Research Ethics Office.

Should you wish to make a modification to the project or request an extension to approval you will need approval for this and should follow the guidance relating to modifying approved applications:
http://www.kcl.ac.uk/innovation/research/support/ethics/applications/modifications.aspx
The circumstances where modification requests are required include the addition/removal of participant groups, additions/removal/changes to research methods, asking for additional data from participants, extensions to the ethical approval period. Any proposed modifications should only be carried out once

full approval for the modification request has been granted.

Any unforeseen ethical problems arising during the course of the project should be reported to the approving committee/panel. In the event of an untoward event or an adverse reaction a full report must be made to the Chair of the approving committee/review panel within one week of the incident.

Please would you also note that we may, for the purposes of audit, contact you from time to time to ascertain the status of your research.

If you have any query about any aspect of this ethical approval, please contact your panel/committee administrator in the first instance (http://www.kcl.ac.uk/innovation/research/support/ethics/contact.aspx). We wish you every success with this work.

With best wishes

Yours sincerely

Catherine Fieulleteau
Senior Research Ethics Officer

Cc: Dr Julia Roberts

Appendix 15. Amendment ethics approval

Helen Jones
10 Batchwood Drive
St. Albans
Hertfordshire AL3 5SA

29 August 2014

Dear Helen,

PNM/12/13-123 A mixed methods study to determine the impact of different workforce structures within University Hospital Trusts on the Clinical Research Nurse workforce.

Thank you for submitting a modifications request form for the above study. I am writing to confirm approval of these. The modifications are broadly summarised below:

1. Section 1.3: Glenn Robert has been named as your new academic supervisor.
2. Section 2.3: Revised completion date of December 2016.
3. Section 2.9: Collection of data in acute, rather than university, hospital NHS trusts.
4. Section 4:
    I. Piloting of study within Cancer Research Network teams rather than four district general hospitals.
    II. Some reordering of survey questions following the pilot study.
5. Section 6.3:
    I. Replacement of abbreviation 'CRN' with 'RN' to reflect changes to the Clinical Research Network.
    II. Recruitment of R&D Directors rather than chief nurses as interviewees.

If you have any queries about this application, please contact the Research Ethics Office.

Yours sincerely,

James Patterson – Senior Research Ethics Officer

Cc: Glenn Robert

Appendix 16. Information sheet – Clinical Research Nurse focus group

INFORMATION SHEET FOR PARTICIPANTS

*REC Reference Number:**PNM/12/13 – 123 A***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

To determine the impact of different workforce structures within acute hospital trusts on the Clinical Research Nurse workforce.

(Research Nurse Information Sheet)

I would like to invite you to participate in this doctoral research project. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the project is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information please do not hesitate to contact me.

The overall aim of this project is to explore the experience of Clinical Research Nurses working within acute NHS trusts in England and Scotland and determine the most effective way to structure the CRN workforce.

This project is being carried out as part of a Doctorate in Healthcare at Kings College London. The researcher manages a team of Clinical Research Nurses at a London Foundation Trust and has been funded by the Biomedical Research Centre at Guys and St Thomas's NHS Foundation Trust.

Questionnaires have already been sent to Lead Research Nurses based at Acute Hospital; Trusts across England. These have been evaluated and from this four organisations have been selected to form the case study phase of the project. You have been approached as you currently work within one of the selected organisations.

Various staff members at the four selected organisations will be approached and asked to take part in this stage of data collection. These include the Lead Research nurse, Clinical Research Nurses, Principal Investigators and the R and D Director. No other staff groups

will be interviewed even if they work as members of your research team. However, their role may be discussed as part of the study.

This section of the research involves Clinical Research Nurses who will be asked to take part in focus group interviews. They have been chosen because it is important to hear directly their experience of working with different structures. You are being approached to take part in this study as you have been identified to the researcher as working within a research nurse or research midwife role.

If you agree to take part you will be asked to take part in one focus group interview. There will be a total of between 5 to 6 research nurses / midwives taking part. This will be held in a meeting room in your organisation and will last no more than one hour. Those who take part will be asked a series of questions about the research nurse workforce within their organisation. Each Interview will be audio taped and transcribed at a later date. Recordings of interviews will be deleted upon transcription. Nothing you say will be directly read by anyone other than the researcher. However, individual anonymous quotes may be included in the final report. Names will not be written on any of the tapes or transcripts and you will be anonymous in any written and verbal reports. All data will be stored to comply with the UK Data Protection Act 1998.

When you agree to take part you will be asked to read this information sheet and will be given an opportunity to ask questions. You will be given this information sheet to keep. By taking part you agree to the interview being recorded and transcribed.

You will not be subject to any risks by agreeing to take part in this project. However, the researcher will discuss with the group at the beginning of the focus group interview the topic of sensitive issues and confidentiality. Participants will be asked not to discuss the content of the focus group interview outside of the group. Should sensitive issues be disclosed the researcher will include a debriefing session at the end of the discussion which will not be recorded.

You will not benefit directly from taking part in this . However, it is hoped that the results will help to identify the most effective organisational structure for Clinical Research Nurses working within Acute Hospital Trusts. Upon completion of the Doctorate sections will be written up with the aim of having them published in peer reviewed journals. Your Lead

Research Nurse will be kept informed of the results of the study and will be sent copies of any published articles which involve data collection from your organisation.

If you have any questions or require more information about this , please contact the researcher using the following contact details: Helen Jones, Telephone = 07920 806255, or by e mail on Helen.h.jones@kcl.ac.uk

You may also withdraw any data/information you have already provided up until it is transcribed for use in the final report by December 2016.

If this project has harmed you in any way, you can contact King's College London using the details below for further advice and information:

SUPERVISOR:

Professor Glenn Robert
Chair in Healthcare Quality and Improvement,
Kings College London,
Florence Nightingal School of Nursing and Midwifery,
James Clerk Maxwell Building,
57, Waterloo Road,
London. SE1 8WA.
glenn.robert@kcl.ac.uk

Thank you for taking the time to read this Participant Information Sheet.

Appendix 17. Information sheet – Lead Clinical Research Nurse

INFORMATION SHEET FOR PARTICIPANTS

REC Reference Number: ***= PNM/12/13 – 123 A***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

To determine the impact of different workforce structures within Acute Hospital Trusts on the Clinical Research Nurse workforce.

(Lead Clinical Research Nurse Information Sheet)

I would like to invite you to participate in this doctoral project. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the project is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information please do not hesitate to contact me.

The overall aim of this project is to explore the experience of Clinical Research Nurses working within acute NHS trusts in England and Scotland and determine the most effective way to structure the CRN workforce.

This project is being carried out as part of a Doctorate in Healthcare at Kings College London. The researcher manages a team of Clinical Research Nurses at a London Foundation Trust and has been funded by the Biomedical Research Centre at Guys and St Thomas's NHS Foundation Trust.

As you are aware questionnaires have already been sent to Lead Research Nurses based at Acute Hospital Trusts across England, and you have kindly completed this. These have been evaluated and from this four organisations have been selected to form the case study phase of the project. You have been approached as you currently work within one of the selected organisations.

Various staff members at the four selected organisations will be approached and asked to take part in this stage of data collection. These include the Lead Research nurse, Clinical Research Nurses, Principal Investigators and the R and D Manager. No other staff groups will be interviewed even if they work as members of your research team. However, their role may be discussed as part of the study.

This section of the project involves the Lead Research Nurse who will be asked to take part in one to one interviews. They have been chosen because it is important to hear directly their experience and views of the current structure of the research nurse workforce within their organisation. You are being approached to take part in this project as you have been identified to the researcher as fulfilling the role of Lead Research Nurse within your organisation.

If you agree you will be asked to take part in one interview. This will be held in a meeting room in your organisation and will last no more than one hour. Those who take part will be asked a series of questions about the research nurse workforce within their organisation. Each Interview will be audio taped and transcribed at a later date. Recordings of interviews will be deleted upon transcription. Nothing you say will be directly read by anyone other than the researcher. However, individual anonymous quotes may be included in the final report. Names will not be written on any of the tapes or transcripts and you will be anonymous in any written and verbal reports. All data will be stored to comply with the UK Data Protection Act 1998.

When you agree to take part you will be asked to read this information sheet and will be given an opportunity to ask questions. You will be given this information sheet to keep. By taking part you agree to the interview being recorded and transcribed.

You will not be subject to any risks by agreeing to take part. However, the researcher will discuss at the beginning the topic of sensitive issues and confidentiality. Participants will be asked not to discuss the content of the interview outside of the session. Should sensitive issues be disclosed the researcher will include a debriefing session at the end of the interview which will not be recorded.

You may not benefit directly from taking part. However, it is anticipated that the results will help to identify the most effective organisational structure for Clinical Research Nurses working within Acute Hospital Trusts. Upon completion of the Doctorate there will be published outputs in peer reviewed journals. I will keep you as the Lead Research Nurse within your organisation informed concerning the results of the project and send you copies of any published articles. These can then be distributed to others who were involved in the data collection.

If you have any questions or require more information about this, please contact the researcher using the following contact details: Helen Jones, Telephone = 07816 930911, or by e mail on Helen.h.jones@kcl.ac.uk

You may also withdraw any data/information you have already provided up until it is transcribed for use in the final report by June 2016.

If this project has harmed you in any way, you can contact King's College London using the details below for further advice and information:

SUPERVISOR:

Professor Glenn Robert
Chair in Healthcare Quality and Improvement,
Kings College London,
Florence Nightingale School of Nursing and Midwifery,
James Clerk Maxwell Building,
57, Waterloo Road,
London. SE1 8WA.
glenn.robert@kcl.ac.uk

Thank you for taking the time to read this Participant Information Sheet.

Appendix 18. Information sheet – Principal Investigator

INFORMATION SHEET FOR PARTICIPANTS

*REC Reference Number:= **PNM/12/13 – 123 A***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

To determine the impact of different workforce structures within Acute Hospital Trusts on the Clinical Research Nurse workforce.

(Principal Investigator Information Sheet)

I would like to invite you to participate in this doctoral research project. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information please do not hesitate to contact me.

The overall aim of this project is to explore the experience of Clinical Research Nurses working within acute NHS trusts in England and Scotland and determine the most effective way to structure the CRN workforce.

This project is being carried out as part of a Doctorate in Healthcare at Kings College London. The researcher manages a team of Clinical Research Nurses at a London Foundation Trust and has been funded by the Biomedical Research Centre at Guys and St Thomas's NHS Foundation Trust.

Questionnaires have already been sent to Lead Research Nurses based at Acute Hospital Trusts across England. These have been evaluated and from this four organisations have been selected to form the case study phase of the project. You have been approached as you currently work within one of the selected organisations.

Various staff members at the four selected organisations will be approached and asked to take part in this stage of data collection. These include the Lead Research nurse, Clinical Research Nurses, Principal Investigators and the R and D Manager. No other staff groups will be interviewed even if they work as members of your research team. However, their role may be discussed as part of the study.

This phase of the project involves Principal Investigators who will be asked to take part in one to one interviews. They have been chosen because it is important to hear directly about their experience and perception of carrying out research studies within the current organisational structure. You are being approached to take part as you have been identified to the researcher as fulfilling the role of a Principal Investigator for research studies within your organisation.

If you agree you will be asked to take part in one interview. This will be held in a meeting room in your organisation and will last no more than one hour and you will be asked a series of questions about your experience of working as a Principal Investigator on research studies supported by research nurses within your organisation. Each Interview will be audio taped and transcribed at a later date. Recordings of interviews will be deleted upon transcription. Nothing you say will be directly read by anyone other than the researcher. However, individual anonymous quotes may be included in the final report. Names will not be written on any of the tapes or transcripts and you will be anonymous in any written and verbal reports of the research. All data will be stored to comply with the UK Data Protection Act 1998.

When you agree to take part you will be asked to read this information sheet and will be given an opportunity to ask questions. You will be given this information sheet to keep. By taking part you agree to the interview being recorded and transcribed.

You will not be subject to any risks by agreeing to take part in this. However, the researcher will discuss at the beginning the topic of sensitive issues and confidentiality. Participants will be asked not to discuss the content of the interview outside of the session. Should sensitive issues be disclosed the researcher will include a debriefing session at the end of the interview which will not be recorded.

You may not benefit directly from taking part in this project. However, it is anticipated that the results will help to identify the most effective organisational structure for Clinical Research Nurses working within Acute Hospital Trusts. Upon completion of the Doctorate there will be published outputs in peer reviewed journals. The Lead Research Nurse within your organisation will be kept informed of the results and will be sent copies of any published articles

If you have any questions or require more information about this project, please contact the researcher using the following contact details: Helen Jones, Telephone = 07816 930911, or by e mail on Helen.h.jones@kcl.ac.uk

You may also withdraw any data/information you have already provided up until it is transcribed for use in the final report by June 2016.

If this project has harmed you in any way, you can contact King's College London using the details below for further advice and information:

SUPERVISOR:

Professor Glenn Robert
Chair in Healthcare Quality and Improvement,
Kings College London,
Florence Nightingale School of Nursing and Midwifery,
James Clerk Maxwell Building,
57, Waterloo Road,
London. SE1 8WA.
glenn.robert@kcl.ac.uk

Thank you for taking the time to read this Participant Information Sheet.

Appendix 19. Information sheet – R&D Director

INFORMATION SHEET FOR PARTICIPANTS

*REC Reference Number **PNM/12/13 - 123***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

To determine the impact of different workforce structures within Acute Hospital Trusts on the Clinical Research Nurse workforce.

(R and D Director Information Sheet)

I would like to invite you to participate in this doctoral project. You should only participate if you want to and choosing not to take part will not disadvantage you in any way. Before you decide whether you want to take part, it is important for you to understand why the project is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. If there is anything that is not clear or if you would like more information please do not hesitate to contact me.

The overall aim of this project is to explore the experience of Clinical Research Nurses working within acute NHS trusts in England and Scotland and determine the most effective way to structure the CRN workforce.

This project is being carried out as part of a Doctorate in Healthcare at Kings College London. The researcher manages a team of Clinical Research Nurses at a London Foundation Trust and has been funded by the Biomedical Research Centre at Guys and St Thomas's NHS Foundation Trust.

As you are aware questionnaires have already been sent to Lead Research Nurses based at Acute Hospital Trusts across England, and you have kindly completed this. These have been evaluated and from this four organisations have been selected to form the case study phase of the project. You have been approached as you currently work within one of the selected organisations.

Various staff members at the four selected organisations will be approached and asked to take part in this stage of data collection. These include the Lead Research nurse, Clinical Research Nurses, Principal Investigators and the R and D Manager. No other staff groups will be interviewed even if they work as members of your research team. However, their role may be discussed as part of the study.

This section of the project involves R and D Directors who will be asked to take part in one to one interviews. They have been chosen because it is important to hear directly their experience and perception of the research nurse workforce within their organisation. You are being approached to take part in this study as you have been identified to the researcher as fulfilling the role of R and D Director within your organisation.

If you agree you will be asked to take part in one interview. This will be held in a meeting room in your organisation and will last no more than one hour. Those who take part will be asked a series of questions about the research nurse workforce within their organisation. Each Interview will be audio taped and transcribed at a later date. Recordings of interviews will be deleted upon transcription. Nothing you say will be directly read by anyone other than the researcher. However, individual anonymous quotes may be included in the final report. Names will not be written on any of the tapes or transcripts and you will be anonymous in any written and verbal reports. All data will be stored to comply with the UK Data Protection Act 1998.

When you agree to take part you will be asked to read this information sheet and will be given an opportunity to ask questions. You will be given this information sheet to keep. By taking part you agree to the interview being recorded and transcribed.

You will not be subject to any risks by agreeing to take part. However, the researcher will discuss at the beginning the topic of sensitive issues and confidentiality. Participants will be asked not to discuss the content of the interview outside of the session. Should sensitive issues be disclosed the researcher will include a debriefing session at the end of the interview which will not be recorded.

You may not benefit directly from taking part. However, it is anticipated that the results will help to identify the most effective organisational structure for Clinical Research Nurses working within Acute Hospital Trusts. Upon completion of the Doctorate there will be published outputs in peer reviewed journals. I will keep your Lead Research Nurse within your organisation informed concerning the results of the project and send them copies of any published articles. These can then be distributed to others who were involved in the data collection.

If you have any questions or require more information about this, please contact the researcher using the following contact details: Helen Jones, Telephone = 07816 930911 , or by e mail on Helen.h.jones@kcl.ac.uk

You may also withdraw any data/information you have already provided up until it is transcribed for use in the final report by June 2016.

If this project has harmed you in any way, you can contact King's College London using the details below for further advice and information:

SUPERVISOR:

Professor Glenn Robert
Chair in Healthcare Quality and Innovation
Kings College London,
Florence Nightingale School of Nursing and Midwifery,
James Clerk Maxwell Building,
57, Waterloo Road,
London. SE1 8WA.
glenn.robert@kcl.ac.uk

Thank you for taking the time to read this Participant Information Sheet.

Appendix 20. Phase 2 interview & focus group question schedule

Case study

Lead CRN Interview schedule content

Thank you for agreeing to take part in this interview. I realise you are very busy so I am grateful for your time. Just to confirm, this research is part of my Doctorate studies at Kings College London. I am examining the current structure of Research Nurse Teams around the UK. I have been a research nurse for 20 years so have seen the role and Infrastructure greatly develop over this time. This interview will take approximately 60 minutes and with your agreement will be recorded. I will also take a few notes as prompts for me. If at any point during the interview you wish me to pause or stop please let me know. All data will be anonymised in any publications or presentations

GIVE INFORMATION SHEET – WILL ALSO SEND PRIOR TO VISIT
CHECK IF ANY FURTHER QUESTIONS THEN CHECK VERBAL CONSENT
TURN ON RECORDING DEVICE
SO I AM NOW GOING TO START RECORDING
TURN ON RECORDING DEVICE – **THE RECORDING DEVICE IS NOW ON SO EVERYTHING FROM THIS POINT ON WILL BE RECORDED**
Could you just clarify your title and the length of time you have been in post.

You have already completed the initial questionnaire survey I sent out a few months ago and the follow on from that are some interviews. The topics I will cover will be structured around a quality framework to examine your organisation in more depth. I am using core questions at all sites and then adding further questions as the interview progresses to gain more information about some of the points we discuss. The framework I am using looks at the 6 challenges of quality improvement so I will go through each one separately.

Structural:

Question = in the survey you described the current structure of the CRN workforce
As comprising (**taken from survey responses**) research nurses working in a structure of (**taken from survey responses**)
I want to explore the effectiveness of this. Could you further explain this structure and describe to me whether you feel this structure works.
How has it grown and developed and do you have any future plans in place to change it?
Is the size of your workforce stable or are new roles created at any point?

Prompts to include:

i) Decision making process regarding funding of new posts
ii) Amount of non clinical roles?
iii) Funding challenges
iv) Influences on current structure:
    - External e.g. – NIHR
    - Funding
    - R and D
    - Academic
v) Relationship with other nurses not within research:
    - Clinical
    - Managerial
vi) Future plans

Your role:

How long have you been in your current role?
Could you explain how your role is structured and what accountability and line management arrangements you have in place?
Do you link into or report to the Chief Nurses Office?
Do you attend any trust wide senior nurse meetings?
Is your Chief Nurse aware of the Research Nurse role and the workforce you have here?

Educational

Question = what is the culture of education for nurses within the organisation? By that I mean what support and importance does it get.
Question = Your completed survey provided information concerning the induction and ongoing training available for the research nurse workforce as well as support for academic courses. How well do you think this prepares and updates them for their role?

Prompts to include:

i) Comparison between treatment of research nurses and clinical nurses – is it the same?
ii) Do research nurses engage with the educational opportunities available – internal and external?

iii) Do you have any research nurses employed by your partner university? If yes - Explore the relationship between the university and nursing workforce? Are there any difficulties ?

iv) Explore the importance given to academic development.

Culture:

Question = what is the importance associated with research across your organisation and how much value is put on it from a nursing perspective?

Prompts to include:

i) Explore the culture of research across the organisation?
   - Is it important or valued?
   - Engagement of clinical staff
   - Understanding of requirements – e.g. – clinic space Understanding of Research Nurse role.

ii) Support and facilitation from non research colleagues, especially clinical nurses.

iii) Awareness for research and current infrastructure from non research staff

iv) Support and engagement with national initiatives – e.g. International Clinical trials day. If events are put on are they well supported?

v) What visibility do research nurses have at a senior level?

Emotional:

Question = please outline the patient recruitment strategies used across the CRN workforce here.

Please outline the process of whether and in what way none research colleagues are engaged in research

Prompts to include:

i) Challenge of recruitment targets

ii) Funding determined by research activity = recruited patients. How is this managed/accepted by researchers?

iii) Engagements of wider clinician team and impact of medical rotations and engagement with research governance requirements.

Political:

Question = I now wish to explore the interaction of research and non research teams in different clinical areas. How embedded if at all are the CRNs in the clinical workforce?

Prompts to include:

i) Impact of historical them and us within nursing.

ii) Reactions of Consultants to any changes in CRN workforce structure – historical Consultant "ownership" of their CRN.

iii) Process of empowering research staff

iv) Do CRNs feel empowered to raise issues within their teams?

v) Team politics – relationships in teams between senior colleagues and Consultants – impact on CRN team.

Physical and Technological Challenge:

Question = in your completed survey you described the recent developments within technology that have occurred across your organisation.

You mentioned the introduction of a clinical portal. Could you explain this in more detail please ? (Question 20)

How easily, if at all, do you think these have been incorporated into the research process?

Prompts to include:

i) IT developments being used in research
   - Electronic Case Report Forms (CRFs).

ii) Challenge of electronic patient notes
   - Advantages / disadvantages
   - How does this impact on research data collection?
   - Paper requirements of studies (how overcome):
     - Consent forms
     - GP Letters
     - Recording patient visits

iii) Use of hand held devices (if any)

iv) Physical environment :
   - Logistics of where to see patients within outpatient clinics
   - Transport of required equipment
   - Travelling across site

v) Accessing other organisations:
   - Honorary / Research passports

Thank you that is all my questions, is there anything you would like to add? Process now is for me to transcribe this interview and then send you a copy so that you can confirm it is an accurate account of what we have discussed today.

Many thanks again.

End of interview.

Principal Investigator Interview schedule content

Thank you for agreeing to take part in this interview. I realise you are very busy so I am grateful for your time. Just to confirm, this research is part of my Doctorate studies at Kings College London. I am examining the current structure of Research Nurse Teams around the UK. I have been a research nurse for 20 years so have seen the role and Infrastructure greatly develop over this time. This interview will take no more than 60 minutes and with your agreement will be recorded. I will also take a few notes as prompts for me. If at any point during the interview you wish me to pause or stop please let me know.

GIVE INFORMATION SHEET – WILL ALSO SEND PRIOR TO VISIT
CHECK IF ANY FURTHER QUESTIONS THEN CHECK VERBAL CONSENT
TURN ON RECORDING DEVICE
SO I AM NOW GOING TO START RECORDING
TURN ON RECORDING DEVICE – **THE RECORDING DEVICE IS NOW ON SO EVERYTHING FROM THIS POINT ON WILL BE RECORDED**
Could you just clarify your title and the length of time you have been in post.

Your Lead Clinical Research Nurse, has already completed the initial questionnaire survey I sent out a few months ago and the follow on from that are some interviews. The topics I will cover will be structured around a quality framework to examine the organisational structure of your Clinical Research Nurse (CRN) workforce in more depth. I am using core questions at all sites and then adding further questions as the interview progresses to gain more information about some of the points we discuss.
The framework I am using looks at the 6 challenges of quality improvement so I will go through each one separately.

Structural:

Question = in the survey your Lead CRN described the current structure of the CRN workforce as (**taken from survey responses**)
I want to explore the effectiveness of this. Could you further explain this structure and describe to me whether you feel this structure works.
What is the structure of your research nurse support?

Can you describe to me whether you feel it is an effective way to support recruitment into research studies?

What is the process for introducing new studies to the team portfolio and are the research nurses involved?

Prompts to include:

i) Are you aware of the size of the CRN workforce in your organisation?
ii) What is the process regarding funding of new posts?
iii) How do you organise additional research nurse support for your studies?
iv) How do you manage any funding that you might receive for new CRN posts in order to appoint an individual? Who do you approach?
v) Funding challenges
vi) Influences on current structure:
    - External e.g. – NIHR
    - Funding
    - R and D
    - Academic
vii) Are you aware of the relationship that CRNs have with other nurses not within research:
    - Clinical or managerial
viii) Future plans

Educational

Question = What educational support do the CRNs receive in your organisation? Do you think that the education available helps to support the development of a competent Research Nurse workforce ?

How important do you think id their continuing academic development?

Question = The completed survey provided information concerning the induction and ongoing training available for the research nurse workforce as well as support for academic courses. How well do you think this prepares and updates them for their role?

Prompts to include:

i) Do the CRNs who work on your studies attend appropriate training courses to ensure they possess the relevant knowledge?
ii) Explore any PI involvement in the training of the CRNs – formal or informal.

iii) Do the PI's help facilitate learning opportunities – e.g. – assist with funding to attend relevant conferences.

Culture:

Question = what is the importance associated with research across your 0rganisation and how much value is put on it ?

Prompts to include:

i) Explore the culture of research across the organisation?
ii) Is it important or valued?
iii) Engagement of clinical staff
iv) Understanding of requirements – e.g. – clinic space
v) Support and facilitation from non research colleagues
vi) Awareness for research and current infrastructure from non research staff
vii) Support and engagement with national initiatives – e.g. International Clinical trials day

Emotional:

Question = Please comment on the response and reception that CRNs receive in the clinical environment towards research.

Please outline the process of how none research colleagues are engaged in research

Prompts to include:

i) Are the CRNs easily able to carry out their patient study visits within a clinical service?
ii) Challenge of recruitment targets
iii) Funding determined by research activity = recruited patients. How is this managed/accepted by researchers?
iv) Engagements of wider clinician team and impact of medical rotations and engagement with research governance requirements.

Political:

Question = I now wish to explore the interaction of research and non research teams in different clinical areas. How embedded if at all are the CRNs in the clinical workforce?

Prompts to include:

i) Reactions of Consultants to any changes in CRN workforce structure – historical Consultant "ownership" of their CRN.

ii) Process of empowering research staff
iii) Do CRNs attend research team meetings? If so what is their remit and input?
iv) Team politics – relationships in teams between senior colleagues and Consultants – impact on CRN team.

Physical and Technological Challenge:

Question = in your completed survey the Lead CRN described the recent developments within technology that have occurred across your organisation. How easily, if at all, do you think these have been incorporated into the research process?

Prompts to include:

i) IT developments being used in research
    i. Electronic Case Report Forms (CRFs).
ii) Challenge of electronic patient notes
    i. Advantages / disadvantages
    ii. Awareness of how this impacts on research data collection?
iii) Use of hand held devices (if any)
iv) Physical environment :
    I. Logistics of where to see patients within outpatient clinics – what difficulties if any do the CRNs experience.
    II. What is the PI awareness regarding the impact of technological changes in research.

Thank you that is all my questions, is there anything you would like to add? Process now is for me to transcribe this interview and then send you a copy so that you can confirm it is an accurate account of what we have discussed today.

Many thanks again.

End of interview.

R and D Director Interview schedule content

Thank you for agreeing to take part in this interview. I realise you are very busy so I am grateful for your time. Just to confirm, this research is part of my Doctorate studies at Kings College London. I am examining the current structure of Research Nurse Teams around the UK. I have been a research nurse for 20 years so have seen the role and Infrastructure greatly develop over this time. This interview will take a maximum of 60 minutes and with your agreement will be recorded. I will also take a few notes as prompts for me. If at any point during the interview you wish me to pause or stop please let me know.

GIVE INFORMATION SHEET – WILL ALSO SEND PRIOR TO VISIT
CHECK IF ANY FURTHER QUESTIONS THEN CHECK VERBAL CONSENT
TURN ON RECORDING DEVICE
SO I AM NOW GOING TO START RECORDING
TURN ON RECORDING DEVICE – **THE RECORDING DEVICE IS NOW ON SO EVERYTHING FROM THIS POINT ON WILL BE RECORDED**
Could you just clarify your title and the length of time you have been in post.

Your Lead Clinical Research Nurse, has already completed the initial questionnaire survey I sent out a few months ago and the follow on from that are some interviews. The topics I will cover will be structured around a quality framework to examine the organisational structure of your Clinical Research Nurse (CRN) workforce in more depth. I am using core questions at all sites and then adding further questions as the interview progresses to gain more information about some of the points we discuss.
The framework I am using looks at the 6 challenges of quality improvement so I will go through each one separately.

Structural:

Question =
Can you explain how research is delivered within your organisation?
How do you incorporate NIHR metrics into your strategy?
In the survey your Lead CRN described the current structure of the CRN workforce as comprising of (**taken from survey responses**)

I want to explore the effectiveness of this. Could you further explain this structure and describe to me whether you feel this structure works.

Prompts to include:

i) What is the funding which supports CRN posts?

ii) Awareness of leadership of CRN workforce. Awareness of management structure of CRN workforce.

iii) Is the CRN workforce linked to the clinical workforce?

iv) Understanding of national and local infrastructure for research which supports the local CRN workforce

- NIHR
- Research Networks.
- Research and Development department

v) Are you aware of the relationship that CRNs have with other nurses not within research:

- Clinical or managerial

Educational

Question = Are you aware of the educational support that CRNs receive in your organisation? Do you think that the education available helps to support the development of the CRNs?

Question = The completed survey provided information concerning the induction and ongoing training available for the research nurse workforce as well as support for academic courses. Were you aware that this is in place?

Prompts to include:

i) Is it important for the CRN workforce to be able to access relevant training courses?

ii) Are CRNs able to access the same funding streams for training as clinical nurses?

Culture:

Question = what is the importance associated with research across your organisation and how much value is put on it?

Prompts to include:

i) Explore the culture of research across the organisation?

- Is it important or valued?

- Engagement of non research nursing staff
- Understanding of requirements – e.g. – clinic space

ii) Support and facilitation from non research nursing colleagues

iii) Awareness of research and current infrastructure from non research staff

iv) Support and engagement with national initiatives – e.g. International Clinical trials day

Emotional:

Question = I am interested in the response and reception that CRNs receive in the clinical environment towards research. What is your understanding of the reception that CRNs experience when attending the outpatient clinic to see research patients?

Are you aware of whether those not in a research role are engaged in research

Prompts to include:

i) Are the CRNs easily able to carry out their patient study visits within a clinical service?

ii) Understanding of recruitment targets – link with future funding.

iii) Engagements of wider nursing clinician team and engagement with research governance requirements.

Political:

Question = I now wish to explore the interaction of research and non research teams in different clinical areas. What is your awareness of how embedded if at all the CRNs are in the clinical workforce?

Prompts to include:

i) Process of empowering research staff

ii) Relationship of CRNs and non research nurses within the clinical setting.

Physical and Technological Challenge:

Question = in your completed survey the Lead CRN described the recent developments within technology that have occurred across your organisation. How easily, if at all, do you think these have been incorporated into the research process? Has R and D been involved in the development of IT changes to ensure that research requirements are considered?

Prompts to include:

i) IT developments being used in research

i. Electronic Case Report Forms (CRFs).

ii) Challenge of electronic patient notes
    i. Advantages / disadvantages
    ii. Awareness of how this impacts on research data collection?

iii) Use of hand held devices (if any)

iv) Physical environment :
    i) Logistics of where to see patients within outpatient clinics – what difficulties if any do the CRNs experience.
    ii) What is the R and D Director awareness regarding the impact of technological changes in research.

Could you give me an overview of any involvement you have in the support of the research nurse workforce in order to ensure that as an organisation you deliver on NIHR metrics.

Thank you that is all my questions, is there anything you would like to add? Process now is for me to transcribe this interview and then send you a copy so that you can confirm it is an accurate account of what we have discussed today.

Many thanks again.
End of interview.

Clinical Research Nurse – Focus group schedule content

Thank you to everyone for agreeing to take part in this focus group. I realise you are all very busy so I am grateful for your time. Just to confirm, this research is part of my Doctorate studies at Kings College London. I am examining the current structure of Research Nurse Teams around the UK. I have been a research nurse for 20 years so have seen the role and Infrastructure greatly develop over this time. This focus group will take about 60 minutes and with agreement from all of you will be recorded. I will also take a few notes as prompts for me. If at any point during the interview anyone would like me to pause or stop please let me know. I would also add that we ensure that only one person speaks at one time in order to ensure that the recording device picks everything up. I also wanted to confirm that all data will be anonymised in any publications.

GIVE INFORMATION SHEET – WILL ALSO SEND PRIOR TO VISIT
CHECK IF ANY FURTHER QUESTIONS THEN CHECK VERBAL CONSENT
ASK THAT NOTHING DISCUSSED DURING THE FOCUS GROUP IS TAKEN OUT OF THIS SESSION AND DISCUSSED WITH OTHERS.
SO I AM NOW GOING TO START RECORDING
TURN ON RECORDING DEVICE – **THE RECORDING DEVICE IS NOW ON SO EVERYTHING FROM THIS POINT ON WILL BE RECORDED.**
Could I start by asking each if you to confirm their clinical area, band, length of time in post and whether this is your first research nurse post.

Your Lead Clinical Research Nurse, has already completed the initial questionnaire survey I sent out a few months ago and the follow on from that are some interviews. The topics I will cover will be structured around a quality framework to examine the organisational structure of your Clinical Research Nurse (CRN) workforce in more depth. I am using core questions at all sites and then adding further questions as the interview progresses to gain more information about some of the points we discuss.

Areas to be covered in the interview within each of the challenges are:

Structural:

Question = in the survey your Lead Research Nurse described the current structure of the CRN workforce as comprising of (**taken from survey responses**).

I want to explore the effectiveness of this. Could you further explain this structure and describe to me whether you feel this structure works.

Prompts to include:

i) Were you aware of the size of the CRN workforce in your organisation?

ii) What is your awareness of the different funding sources behind your roles?

iii) Explore structure and appropriateness of their line management structure.

iv) The research component of your organisation is part of a national infrastructure of BRC / BRU / Research Networks. How, if at all, does this impact on you? (Question to be asked only if appropriate).

v) Aim to explore the structure of their individual research teams – what other research roles are there. Do the teams differ across different clinical areas? Could you each explain the team structure that you work within.

vi) How would you describe your relationship with other nurses not within research:

- Clinical or managerial

vii) Can integration be too successful - asked to carry clinical activities.

viii) Are you aware of any future plans that will impact on the CRN workforce in your organisation?

Educational

Question = what is the culture of education for nurses within the organisation? By that I mean what support and importance does it get.

Question = The completed survey provided information concerning the induction and ongoing training available for the research nurse workforce as well as support for academic courses. How prepared and updated did you feel for your role?

Prompts to include:

i) Comparison between treatment of research nurses and clinical nurses – is it the same?

ii) Do research nurses engage with the educational opportunities available – internal and external?

iii) Explore the relationship between the university and nursing workforce?

iv) Explore what importance the group feels is given to academic development.

v) Is it parallel to the support received by clinical nurses?

Culture:

Question = what is the importance associated with research across your organisation and how much value is put on it from a nursing perspective ?

Prompts to include:

i) Explore the culture of research across the organisation?
   - Is it important or valued?
   - Engagement of clinical staff
   - Understanding of requirements – e.g. – clinic space

ii) Support and facilitation from non research colleagues

iii) Do you wear a uniform and if so what importance do you place on it?

iv) Awareness for research and current infrastructure from non research staff

v) Do clinical nursing colleagues understand the CRN role? Explore answers and reasons why.

vi) Support and engagement with national initiatives – e.g. International Clinical trials day

vii) What visibility do research nurses have at a senior nursing level?

Emotional:

Question = please outline the participant recruitment strategies used across the CRN workforce here.

What attracted each of you to the role? I shall go round and ask everyone individually.

Please outline the process of how none research colleagues are engaged in research

Prompts to include:

i) Challenge of recruitment targets – does this affect the CRN morale?

ii) Please describe your experience of seeing your research participants within an outpatient clinic. Compare to experience on the Clinical Research Facility if present within the organisation.

iii) Engagements of wider clinician team and impact of medical rotations and engagement with research governance requirements.

iv) Emotional involvement with patients – length of follow up impacting on the long term relationship with the patient.

Political:

Question = I now wish to explore the interaction of research and non research teams in different clinical areas. How embedded if at all do you feel in the clinical workforce?

Prompts to include:

i) Impact of historical them and us within nursing.

ii) Reactions of Consultants to any changes in CRN workforce structure – historical Consultant "ownership" of their CRN.

iii) Process of empowering research staff

iv) Do you feel empowered to raise issues within your research teams?

v) Team politics – relationships in teams between senior colleagues and Consultants – impact on the CRN team.

Physical and Technological Challenge:

Question = in the completed survey your Lead CRN described the recent developments within technology that have occurred across your organisation. How easily, if at all, do you think these have been incorporated into the research process?

Prompts to include:

i) IT developments being used in research
    i. Electronic Case Report Forms (CRFs).

ii) Challenge of electronic patient notes
    i. Advantages / disadvantages
    ii. How does this impact on research data collection?
    iii. Paper requirements of studies (how overcome):
        1. Consent forms
        2. GP Letters
        3. Recording patient visits

iii) Use of hand held devices (if any)

iv) Physical environment :
        1. Logistics of where to see patients within outpatient clinics
        2. Transport of required equipment
        3. Travelling across site

v) Accessing other organisations:
        1. Honorary / Research passports

Thank you that is all my questions, is there anything that anyone would like to add? Process now is for me to transcribe this interview and then send you all a copy so that you can confirm it is an accurate account of what we have discussed today.

Many thanks again.

End of interview.

Appendix 21. Data analysis themes and sub themes

Data analysis themes and sub themes – NVIVO analysis

Challenge	Theme	Sub theme	Sources	References
STRUCTURE	Workforce Model	- P.I perspective - CRN perspective - Lead CRN perspective - R&D perspective - Benefits to trust - University appointed CRNs - Chief Nurse awareness	7 4 3 2 5 3 7	33 34 36 7 7 12 14
	Lead CRN role	- Accountability - Impact	6 11	19 38
	Non nursing research roles		12	30
	CRN role		15	36
EDUCATION	Finances		12	31
	Courses		5	11
	Training programmes		6	8
	Impact		3	3
	Culture of education		5	7
CULTURE	Clinical perspective		11	38
	Value of research	- Generally - CRN sense of value	18 2	54 4
	Dedicated space		17	56
	Interaction		18	84
	CRN uniform	- Generally - Professional identity - Patient perspective	6 4 2	26 8 5
	P.I engagement		4	13
	Raising research profile		10	31
EMOTIONS	Relationships	- Generally - Patients	9 5	31 10
	Recruitment		13	29
	Clinical team engagement		6	15
POLITICS	Embedding of CRNs	- Generally - Drawbacks	17 10	41 16
	Raise awareness		6	22
TECHNOLOGY	R&D involvement		2	6

Appendix 22. Case study questionnaire summaries

Case study questionnaire summaries

Case Study 1

Structure

The organisation has a small CRN workforce of 15 post holders. The majority of the generic team are at a band 6 level. The workforce is led by the Research Trials Nurse Manager who is at a band 7 level. When the survey was completed she had held her post for 18 months and was the first post holder. The CRN workforce had not been reviewed.

Despite the small size of their workforce, the CRNs work within numerous clinical areas and 14 specialities were stated in the survey to include Oncology and Haematology, Midwifery and Children, stroke research, respiratory and critical care. Other research roles include a Study Delivery Officer and Research Assistant.

Culture

The Research Trials Nurse Manager scored her response as neutral when asked whether research was considered important by senior nursing staff or staff within the clinical areas. However, she provided no further information to explain her answers. She did confirm that non research colleagues would help to facilitate research by informing CRNs about possible patients who may be suitable for studies. and collecting a small amount of research data if seeing a patient as part of a clinical appointment and were interested in the studies running and willing to remain updated regarding new studies. Overall she thought the CRN role was misunderstood.

She confirmed that the CRNs felt welcome within the clinical environment but were not allocated dedicated space for their patients. Consequently she scored as neutral that patients are sometimes missed as CRNs have not been informed about them. She felt that research is generally misunderstood with little support for its success

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and is low on people's agenda due to the importance given to, and workload implications of, government targets and initiatives.

Education

The Research Trials Nurse Manager confirmed that she felt that the organisation supported the further professional development of nurses. She confirmed that 73% (11/15) of the CRNs had a first degree with just one of her nurses having a Masters degree. On commencement of their post the CRNs attend a full induction programme incorporating trust, nursing and research components. The CRNs were able to access a large amount of generic training including phlebotomy and cannulation skills, I.V drug and chemotherapy administration, basic life support and information governance training. There was also a large amount of research related training available including Human Tissue Act, Mental Capacity Act training, Informed consent for either Clinical Trials of Investigational Medicinal Products (CTIMPs) studies or non CTIMP studies and sample processing skills. CRNs were able to access funding for academic courses but this was more likely to come from external sources such as the NIHR or grant award bodies. Study leave to attend courses was granted according to the trust study leave policy.

Politics

The trust is located on one site and so the CRN workforce are able to concentrate their recruitment from one organisation. The Research Trials Nurse Manager agreed that the CRNs are made to feel accepted within the clinical environment by their nursing colleagues and efforts are made to accommodate their requirements. However, she was less sure as to whether the clinical nurses are happy to help identify suitable patients for studies or collect a small amount of data when requested. She also confirmed that overall the CRNs did find the clinical environment a difficult working environment. She reported that the Principal Investigators (P.I's) are actively involved in all stages of their research projects and regularly check on the overall progress. The CRNs are able to express their own ideas and opinions in teams meetings and have an influence on decisions made. They meet regularly at dedicated research meetings to discuss studies and capacity of CRN workload.

Emotions

The Research Trials Nurse Manager confirmed that staff within the organisation are only somewhat aware of the presence of a dedicated nurse workforce related to research. She was uncertain as to what awareness clinical staff had of the importance of research to the national NHS agenda and how it was currently structured with the organisation and how to access resources. She confirmed that adherence to research governance requirements was good but she was uncertain regarding the attendance of researchers at training sessions and updates.

Technology and Infrastructure

The organisation had not yet implemented electronic patient notes. However, the Research Trials Nurse Manager confirmed that a new "clinical portal" had recently been introduced. This was now used by all research nurses across the organisation but no further details were given regarding its use.

Case Study 2

Structure

The workforce of 120 CRNs is led by the Lead CRN who is at an 8b level. She had held her post for four years but is not the first post holder as the post has been established for approximately 10 years. The CRNs are appointed through the trust either by research teams within the Clinical Research Facility (CRF) or directly by clinical teams.

The organisation initially undertook a full review of their CRN workforce in 2004 when the trust implemented a model they termed the "Research Nurse Framework". Initially the framework set out to identify a clinical manager who would take professional responsibility and line management accountability for the CRNs. A group was established to provide the managers with guidance and information to manage their staff. Since that time R and D has held a register of all CRNs that support research activity including those on a substantive contract and those working

in the organisation through an honorary contract. The workforce has been through a number of iterations and there is now a move to a more centralised model with the CRF being identified as the central appointing point for new CRNs. A number of mainly historical posts remain within the clinical Directorates and so more recently a trust wide Matron role has been established to provide more operational management of these staff.

The CRNs work within numerous clinical areas and 23 specialities were stated in the survey to include Oncology and Haematology, Renal, Cardiovascular, Dermatology, Diabetes, Midwifery and Children, gynaecology, stroke research and critical care. Other research roles include Data Managers, Research Health Care Assistants, Research Pharmacists and Quality Assurance Manager.

Culture

Across the organisation there is very good awareness of research and many staff consider it important and relevant. The CRNs run a number of research awareness sessions to increase clinical staff awareness of the research projects that take place in the clinical environment. This has been very successful and the Lead CRN and colleagues are in the process of developing research champions to work alongside the CRNs to help promote research to clinical colleagues and provide a conduit to identify suitable patients to take part in studies. The research champions will have the opportunity to attend training sessions to support them with this. The CRNs have also worked hard to increase awareness and understanding of their role. The Lead CRN has linked in with the local university to provide placement opportunities for student nurses which will enable them to gain a better understanding of the contributions CRNs make to research and clinical care.

The integration of CRNs within the clinical environment has greatly improved and the Lead CRN strongly agreed that they feel welcome within the clinical environment and are allocated dedicated space to see patients. Therefore CRNs do not encounter difficulties when arranging study visits within the clinical environment and are able to spend the required amount of time with their patients. The Lead CRN has been able to lay the “building blocks” to facilitate the successful integration of research and

"work remains ongoing to ensure this is embedded across the organisation as a whole". The Lead CRN agreed that staff recognise the importance of research and are keen to support its success. Clinical workload does on occasion take precedence but CRNs work hard to build partnership working. This has included supporting clinical pressures over the winter with all CRNs being asked to complete one clinical shift each month.

Education

The Lead CRN confirmed there was a good level of support for the further professional development of all nurses across her organisation. Within research, this included "always actively supporting CRNs through leadership courses as well as Masters in Clinical Research" programmes. There was a feeling that "significant progress had been made over the last few years and there was a clear career pathway for nurses within the organisation with opportunities to gain experience in different points along the patient care pathway".

The Lead CRN was not able to describe the academic profile of her CRN workforce but she was able to confirm that CRNs are able to access funding from internal and external sources for a full range of academic programmes from a BSc degree through to a PhD. Study leave would also be granted to attend the relevant sessions. She was able to confirm that on commencement of their post they attend a full induction programme to include Corporate and Nursing Induction programmes as well as a local and research induction programme. The CRNs were able to access a large amount of generic training programmes including phlebotomy and cannulation skills, basic life support training, intravenous and chemotherapy drug administration, information governance training and any other specific clinical skills as required such as skin biopsy training. There was also a full range of research training available including research governance aspects of Good Clinical Practice (GCP), Human Tissue Act, Mental Capacity Act and the Data Protection Act, as well as training in consent, research methods, ethics and sample processing skills.

Politics

The CRNs work across two main sites but have ease of access to both sites with no adverse effect on the running of research studies. They have a good experience within the clinical environment and are made to feel accepted by their clinical nursing colleagues. The Lead CRN reported that the Principal Investigators (P.I's) are actively involved in all stages of their research projects and regularly check on its progress and the progress of the patients involved. CRNs have an active role within their teams and are able to express their own ideas and opinions within teams meetings and have an influence on decisions being made. The Lead CRN confirmed the PI's and CRNs meet regularly at dedicated research meetings and individual studies are discussed with current capacity of the CRN workload being taken into account.

Emotions

The Lead CRN confirmed that staff within the organisation are very aware of the presence of a dedicated nurse workforce related to research, the structure of research within the organisation and how to access resources to support research studies they may wish to run. She explained that "always more can be done but the CRN workforce is very visible and are empowered to promote research at every given opportunity. Clinical Managers (middle and senior) are aware of the importance of research across the organisation". There are no difficulties related to adherence to research governance requirements and the Lead CRN confirmed she had few concerns regarding the conduct or compliance.

Technology and Infrastructure

At the time the Lead CRN completed the survey (April 2015) the organisation was just in the process of implementing electronic patient notes. Therefore, she was not able to provide any details regarding the impact this had had on research.

Case Study 3

Structure

The organisation has a large CRN workforce of approximately 130 post holders ranging from band 5 to band 8a. Most of the post holders are at a band 6 level – 73% (95/130) and some of these some of these work across the research network region although the exact number was not specified. The majority are appointed through the trust but a small amount (n= 12) are appointed through their partner university. The workforce is led by the Clinical Research Matron who was at an 8a level. At the time of survey completion she had held her post for two years and four months having been the first post holder. At the time of survey completion the CRN workforce was being reviewed but no further information was provided on the form this was taking.

Culture

The Clinical Research Matron strongly agreed that generally research was considered important and relevant within the organisation. However, she did not agree that research is considered important by staff within the clinical areas especially by senior nursing staff at band 8 and above. She confirmed that non research colleagues would help to facilitate research including being aware of some of the research projects, informing CRNs about possible patients and collecting a small amount of research data if they were seeing a patient as part of a clinical appointment. She was unsure as to the understanding from her nursing colleagues of the CRN role but confirmed "we are doing a lot of work across the trust with this and this is improving slowly but surely".

The Clinical Research Matron confirmed that the CRNs feel welcome within the clinical environment and are allocated dedicated space to see research patients. However, she also agreed that the CRNs comment on the difficulty of seeing patients in the clinical environment and being able to spend the required amount of time with them. She clarified this further by stating "this varies across the trust and it is difficult to give one answer. Some areas are very research active and clinical trial

participation is one of the natural treatment options and so finding a clinic room to see a patient is not a problem. Other areas need more education of clinical research and space to see patients' is more of an issue". She agreed that staff recognise the importance of research and are keen to support its success and so did not agree that it was low in people's agenda. She confirmed that "we are working hard and beginning to see results where research is seen as natural treatment choice and not as an optional extra".

Education

The Research Matron confirmed that the professional development of nurses was supported across the organisation. She was unable to fully describe the academic profile of the CRN workforce.

Funding for academic study was difficult to obtain and she confirmed that CRNs were only able to "occasionally" access it either from inside or outside the organisation. Study leave was granted as per the organisations policy and was linked to an individual's appraisal. She did confirm that "there are some departmental differences in how the study leave policy is applied but it gives clear guidance according to the priority, relevance and benefit to the individual".

The Research Matron confirmed that on commencement of their post the CRNs attend a full induction programme to include Corporate and Nursing components as well as a local and research induction programme. They can access a large amount of generic clinical skills training including phlebotomy and cannulation, I.V and chemotherapy drug administration, basic life support and information governance. There was also a full range of research training available including research governance aspects of GCP, Human Tissue Act, Mental Capacity Act and the Data Protection Act, as well as training in consent, research method and sample processing skills. The Research Matron confirmed that there was not a regular ongoing structured training programme in place for the CRNs.

Politics

Some of the CRNs work across more than one organisation as a small number work within the geographical local clinical research network. However, the governance requirements behind this are smooth to set up and no difficulties are encountered. The Research Matron reported a mixed response to questions concerning the engagement of P.Is to their research studies. She agreed that they are actively involved in all stages of their research and regularly check on progress. However, she also agreed that at times it can be difficult to involve the P.Is in the day to day leadership of their projects. She clarified this further by stating "I have included all answers as there are examples of all within our organisation".

The Research Matron agreed that the CRNs did not find the clinical areas a difficult working environment and are made to feel accepted by their nursing colleagues with efforts made to accommodate their requirements and collect a small amount of research data if asked. She further stated "Overall the CRNs are accepted in clinical areas and some nurse specialists are very involved. Some areas are more challenging than others highlighting the need for education and engagement".

Within their research teams, the CRNs are able to express their own ideas and opinions and have an influence on the decisions being made. There are regular research meetings in place where potential studies are discussed and capacity of the CRN workload is considered. The Research Matron also added "again this varies across the trust and therefore a more uniformed structure is required. Regular team meetings work well in the areas they been implemented but in some areas commitment may vary".

Emotions

The Research Matron felt that staff within the organisation were only somewhat aware of the presence of a dedicated nurse workforce related to research, the importance of research to the national NHS agenda and the current structure of research and how to access resources. She explained that they "had recently been given more autonomy from the Clinical Research Network and this will aid there

being only one process to follow for support". Currently the CRNs worked on studies in a varied way across teams. This included some working either just on pharmaceutical, NIHR or single research studies. Adherence to research governance requirements is high with good attendance at training and update sessions.

Technology and Infrastructure

At the time of survey completion a system of electronic patients notes was in the process of being implemented and was in the pilot stage. It was too early to ascertain the impact of this within research. However, the Research Matron confirmed that a Quality Assurance Auditor was actively involved to ensure research aspects were covered. No further details were provided on what this involved.

Case study 4

Structure

The organisation has a small CRN workforce of 24 CRNs who are all appointed within the trust through the R&D department. The team structure is a combination of working within clinical teams with non research colleagues or working directly with Consultants on their research studies. The most senior role is the Lead CRN at band 8a level. He completed the survey but from the responses given it was not clear that his main remit was oncology but had taken on informal support of the remaining CRNs as there was no dedicated post holder to do this. This was revealed during phase 2 of data collection but it is pertinent to mention it here. At the time of survey completion he had been in post for two and half years. The CRNs work within numerous clinical areas and 10 specialities were stated in the survey to include Oncology and Haematology, Cardiovascular, Dermatology, Diabetes, Midwifery and Children, stroke research and critical care. Other research roles include Clinical Trial Co-ordinators, Research Assistants and Research Pharmacists.

A review of the CRN workforce was carried out in April 2014 which co-incited with the national change in the Clinical Research networks. It had been overseen by the

R and D Director with support from the Lead CRN. Within this small changes were made within research teams which mainly comprised of some band 7 roles being downgraded to band 6 roles. No other changes were implemented. During the data collection visit the R and D Director explained that within the review a decision had also been made to look into the possibility of developing a trust wide Lead CRN post. Discussions had started with the Chief Nurse who was supportive of this. However, she had left her post the previous year and now these discussions were on hold while the new Chief Nurse settled into the post.

Culture

The Lead CRN agreed that generally research is considered important and relevant across the organisation. However, he did not think that staff within the clinical areas considered research to be important. He agreed that clinical staff would inform CRNs about patients who may be suitable for studies but would not want to remain updated about new protocols or collect small amounts of research data if seeing patients as part of a clinical appointment. He did not think that the CRN role was understood by nurses and clarified this further by saying "they think its just a simple role for those nurses who can't deal with ward nursing". Regarding the clinical environment he disagreed that CRNs feel welcome within the clinical environment and are allocated dedicated space to see research patients. He agreed that the CRNs comment on the difficulty of seeing patients in the clinical environment and that patients are sometimes missed as they are not informed about them. Questions regarding clinical staff attitude to research were generally scored negatively with the Lead CRN confirming that research is generally misunderstood with little support for its success and it is low on people's agenda due to the importance given to, and workload implications from, government targets and initiatives.

Education

The Lead CRN confirmed that the organisation supported the further professional development of nurses. He was able to fully describe the academic profile of the CRN workforce which included as follows:

- Bsc = 13/24 (54%)
- MSc = 2/24 (8.5%)
- PhD / Professional Doctorate = nil

Funding for academic study appeared easier to access for the higher level study of Masters and PhD/Doctorate but "never" accessible for BSc level degrees. The funding was available internally from the R&D department and the Lead CRN clarified this further by stating it was the "own initiative of the Associate Director of Research to fund academic training". CRNs were also able to receive a complete study leave allowance regardless of the days required.

The Lead CRN confirmed that on commencement of their post the CRNs attend a full induction programme to include Corporate and Nursing components as well as a local and research induction programme. They can access a large amount of generic clinical skills training including phlebotomy and cannulation, I.V and chemotherapy drug administration, basic life support and information governance. There was also some research training available including GCP, Mental Capacity Act, Data Protection Act, and sample processing skills. The CRNs did not appear to be able to access training in consent and sample processing skills. The Lead CRN confirmed that there was not a regular ongoing structured training programme in place for the CRNs.

Politics

The CRNs worked solely within their trust and so there was no requirements to organise access to other sites. There appeared to be good engagement from the P.I's on their studies although the Lead CRN at times felt it was difficult to involve them in the day to day leadership and the CRNs generally take overall management of them. The CRNs generally feel accepted within the clinical environment but still find it a difficult at times. The clinical nurses are not always willing to help identify patients or collect small amounts of data if requested. The research teams meet regularly at dedicated research meetings. Capacity of CRN workload is discussed but the Lead CRN was unsure as to how much they were able to express their own ideas and opinions.

Emotions

Adherence to research governance requirements is high although the Lead CRN was uncertain regarding attendance from all research staff at training and update sessions. He felt that generally staff are only somewhat aware of the presence of a dedicated workforce related to research and the importance of research to the national NHS agenda. He also confirmed that staff were not very aware of the current structure of research within the organisation and the volume of studies currently running. Currently the CRNs are assigned to a mixed portfolio of NIHR and Pharmaceutical studies.

Technology and Infrastructure

The organisation had recently implemented their own patient data system although no details were given as to what this involved. They had also recently attempted to introduce the EDGE research management system but this had failed due to the IT infrastructure not being able to support it.